

Gamma Irradiation of Liquid IGIV in the Absence  
 or Presence of Ascorbate Alone or in Addition to Gly-Gly

Liquid IGIV, Reduced 5-15%

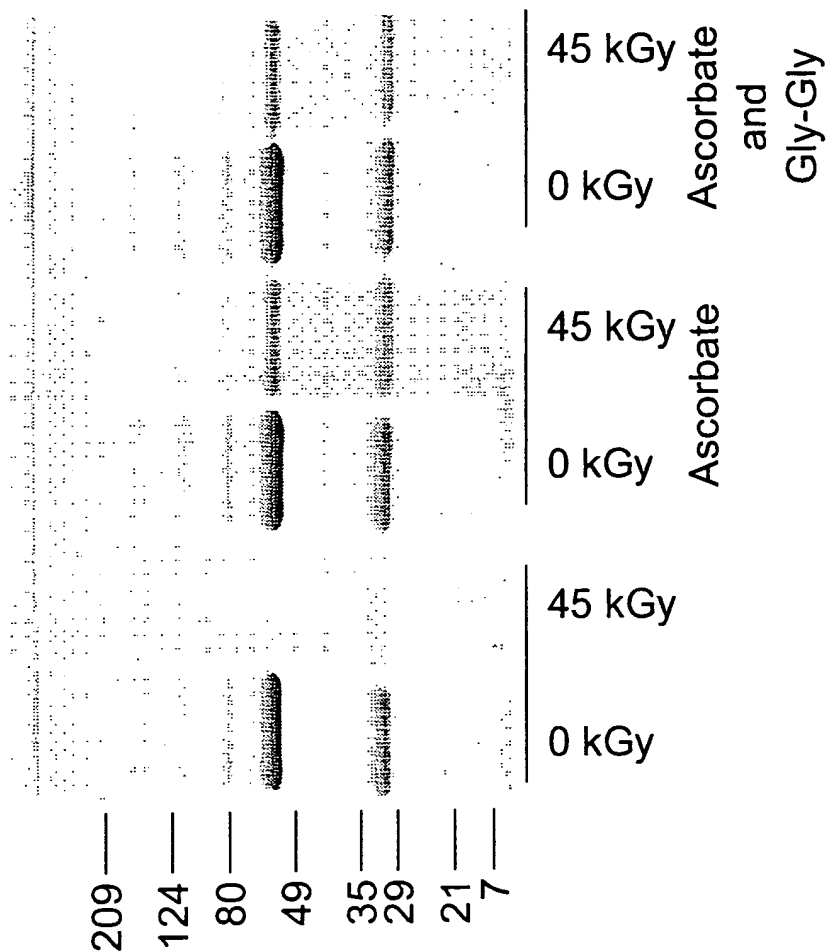


FIG. 1A

Gamma Irradiation of Liquid IGIV in the Absence or  
 Presence of Ascorbate Alone or in Addition to Gly-Gly

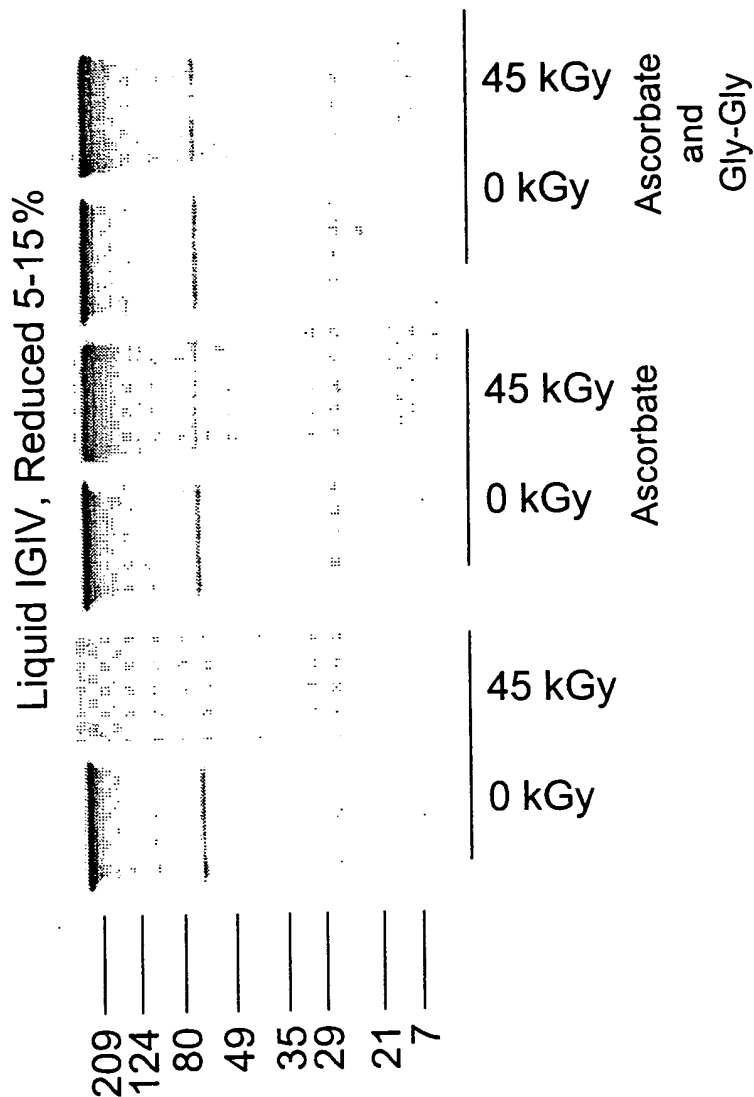


FIG. 1B

Gamma Irradiation of a Glycosidase In the Presence of Ascorbate and Gly-Gly

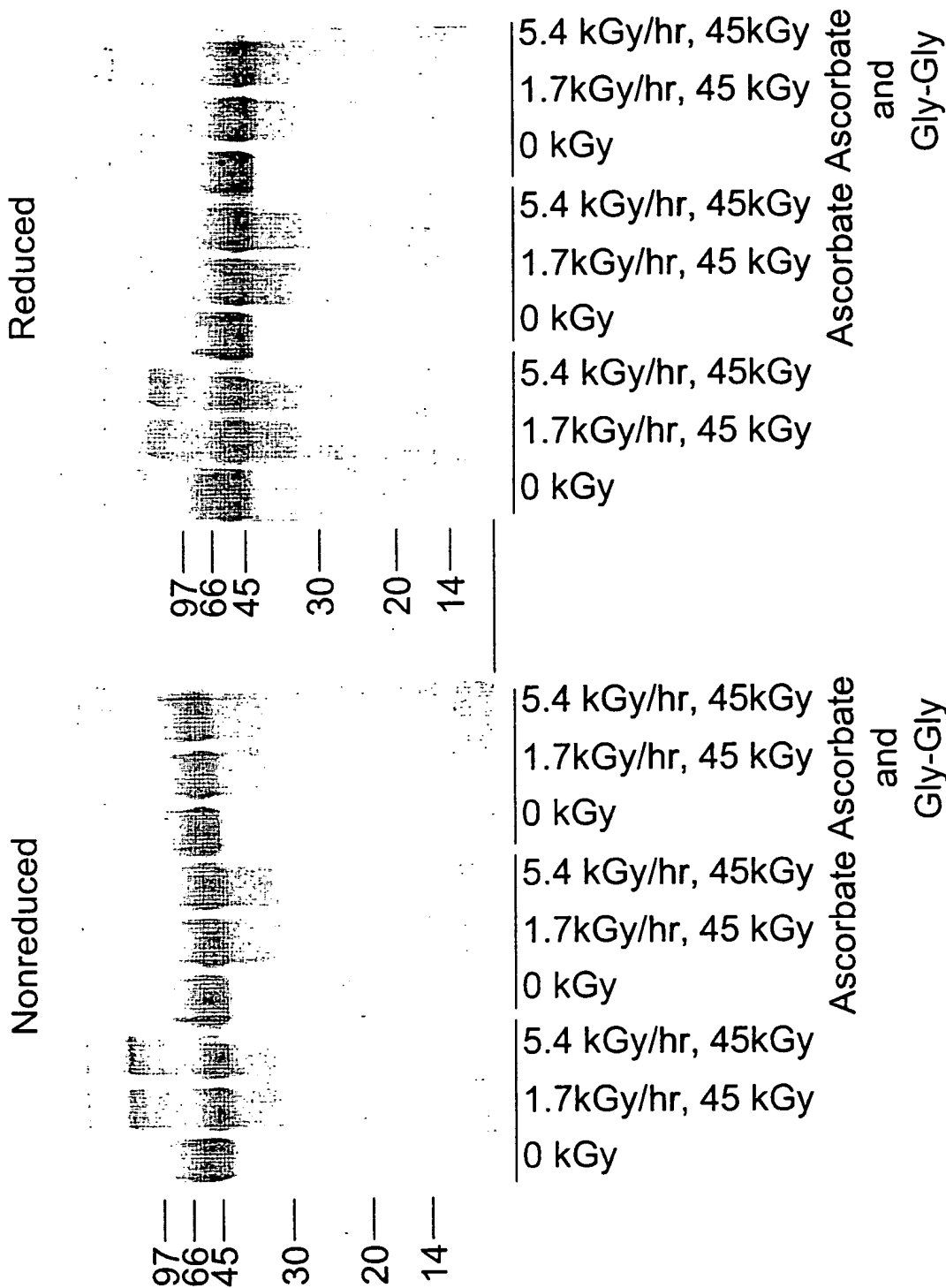


FIG. 2B

FIG. 2A

Gamma Irradiation of a Sulfatase  
 In the Presence of Ascorbate and Gly-Gly

Reduced

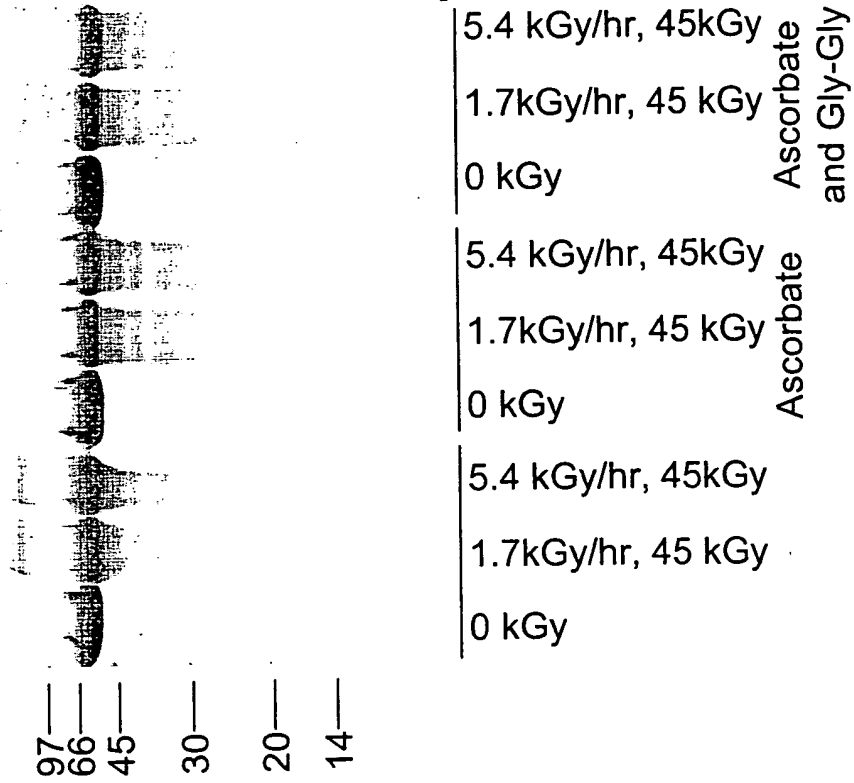


FIG. 3

Gamma Irradiation of a Galactosidase In the Presence or Absence of Ascorbate  
 Alone or in Combination with Gly-Gly

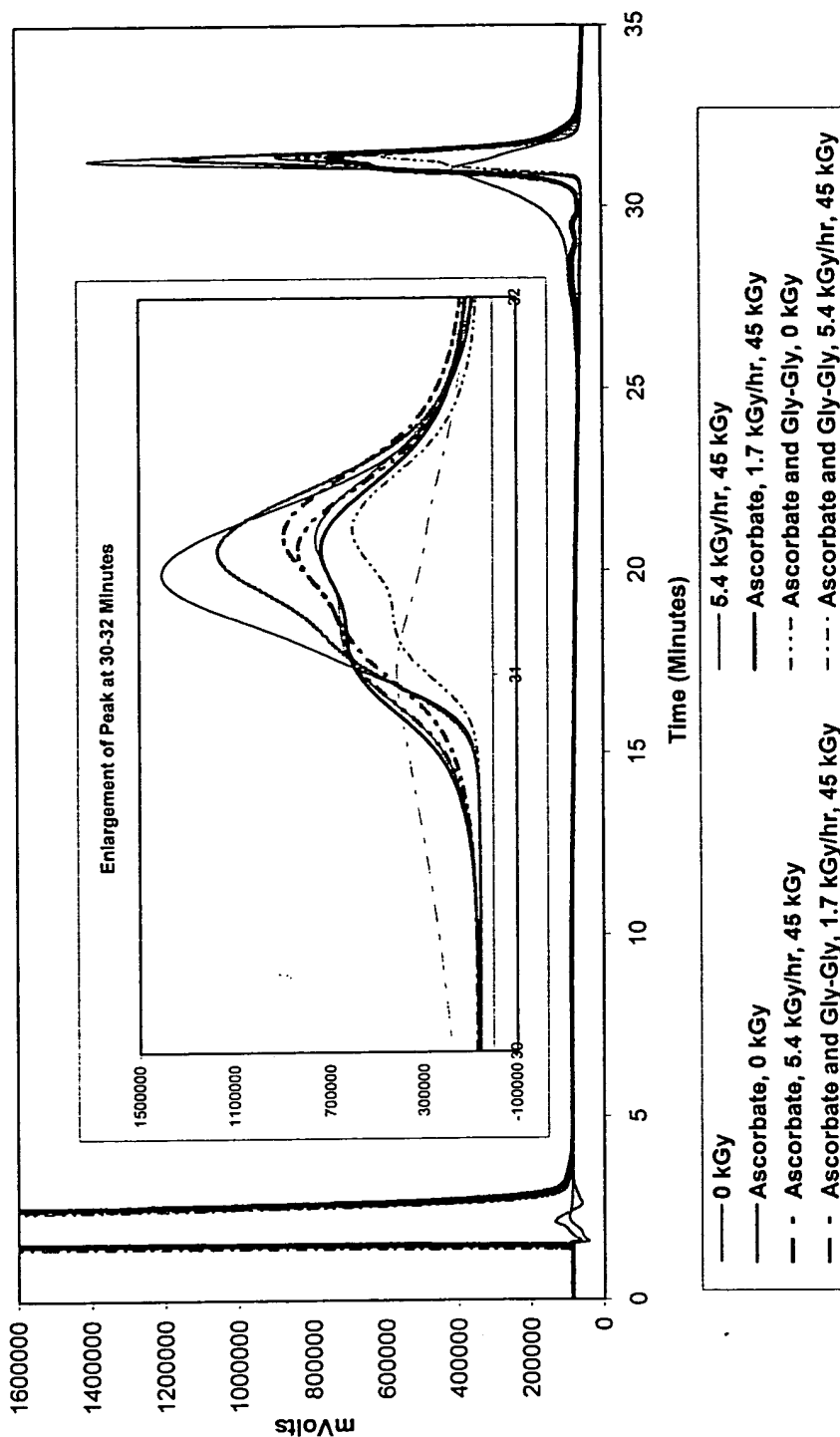


FIG. 4

Gamma Irradiation of Immobilized Anti-Insulin Monoclonal Antibody with Varying  
 Ascorbate Concentrations in the Presence or  
 Absence of 1.5mM Uric Acid

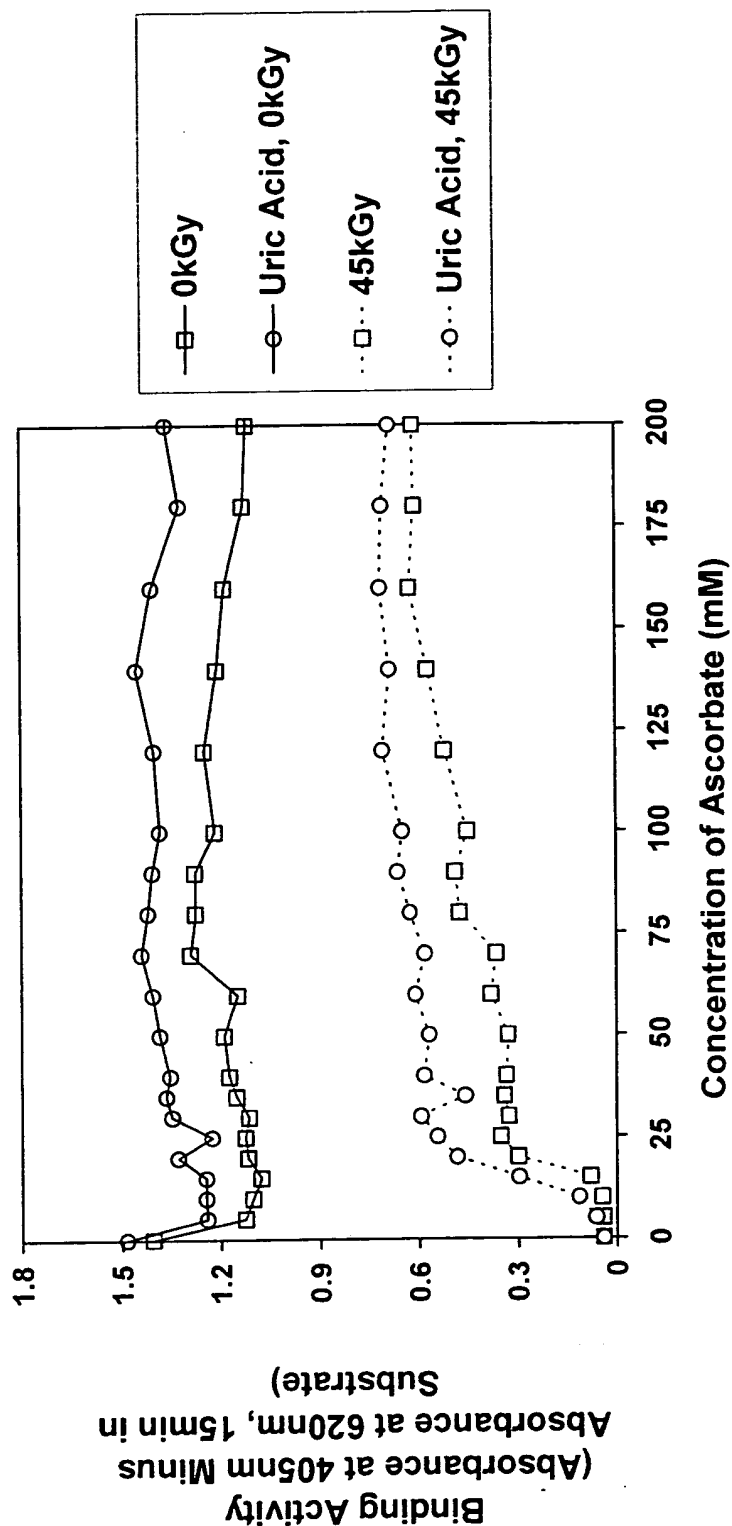


FIG. 5

Gamma Irradiation of Immobilized Anti-Insulin Monoclonal Antibody with Varying  
Ascorbate Concentrations in the Presence  
or Absence of 2.25mM Uric Acid

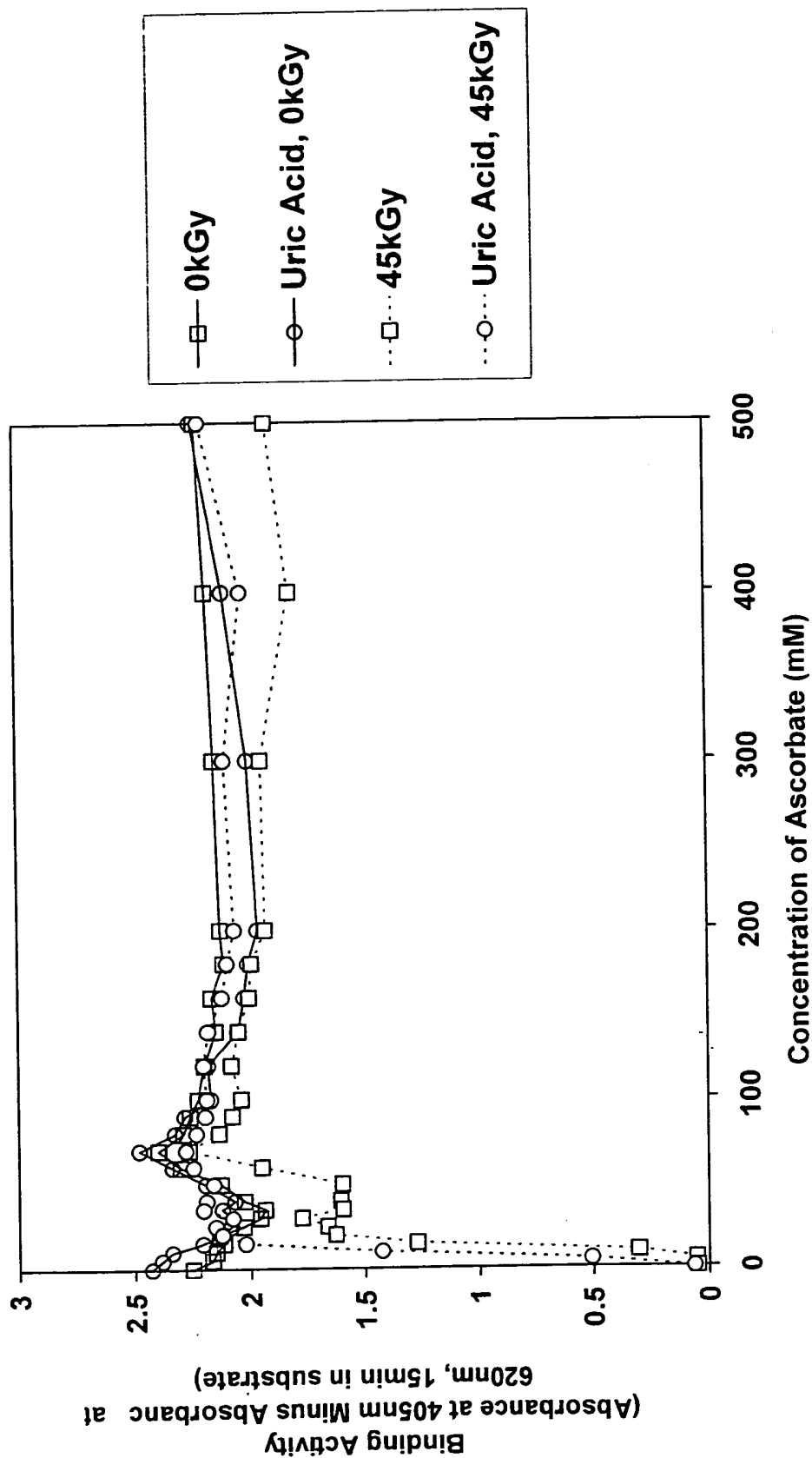


FIG. 6A

Gamma Irradiation of a Lyophilized Galactosidase  
In the Absence of Stabilizers

Reduced & Non-Reduced, 10%

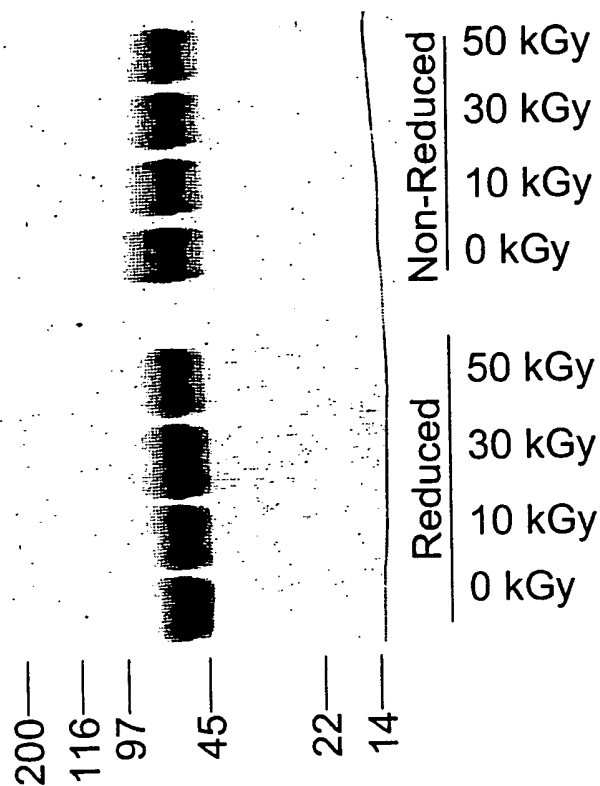


FIG. 6B



Gamma Irradiation of a Lyophilized Galactosidase In the  
 Presence of 200mM Ascorbate  
 Reduced & Non-Reduced, 10%

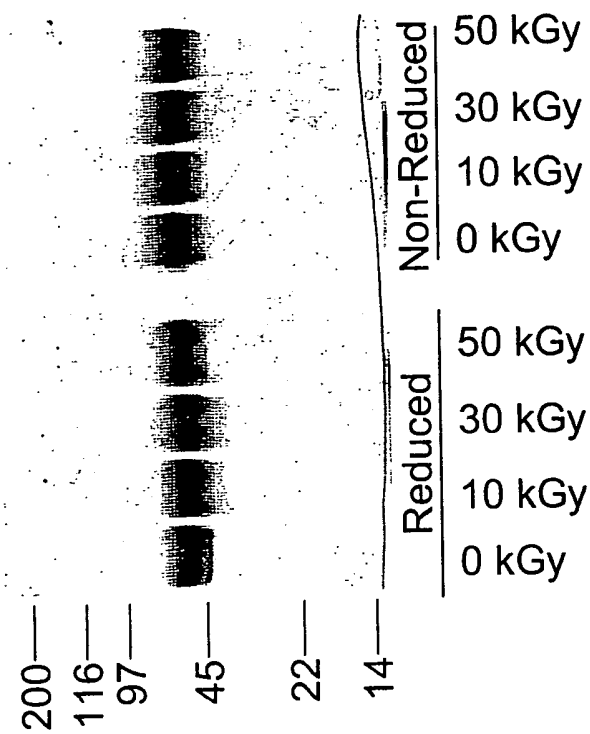


FIG. 6C

Gamma Irradiation of a Lyophilized Galactosidase In the  
 Presence of 200mM Ascorbate and 200mM Gly-Gly

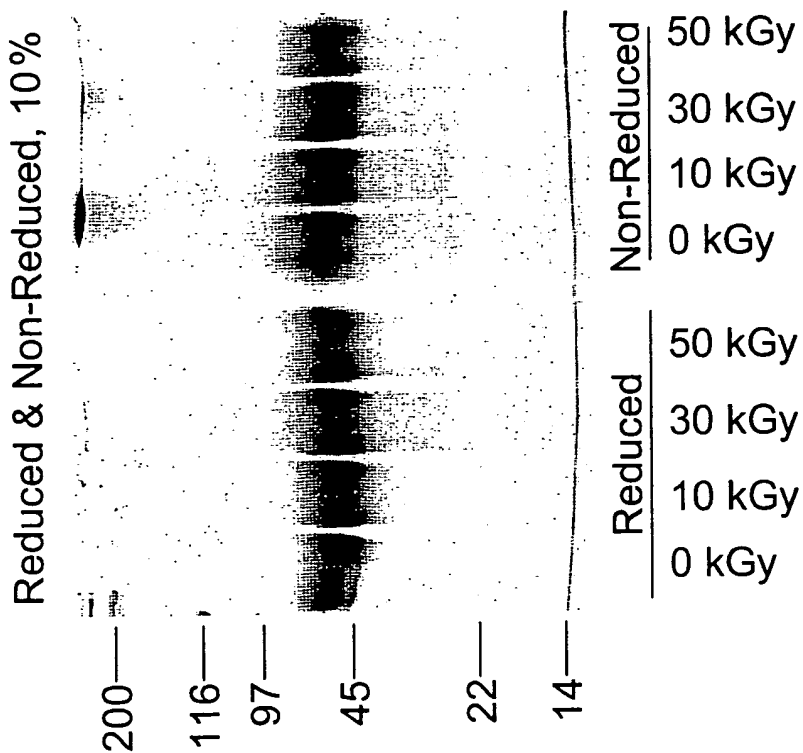


FIG. 7A

Gamma Irradiation of a Galactosidase in the Absence or Presence of  
Ascorbate Alone or in Combination with Gly-Gly

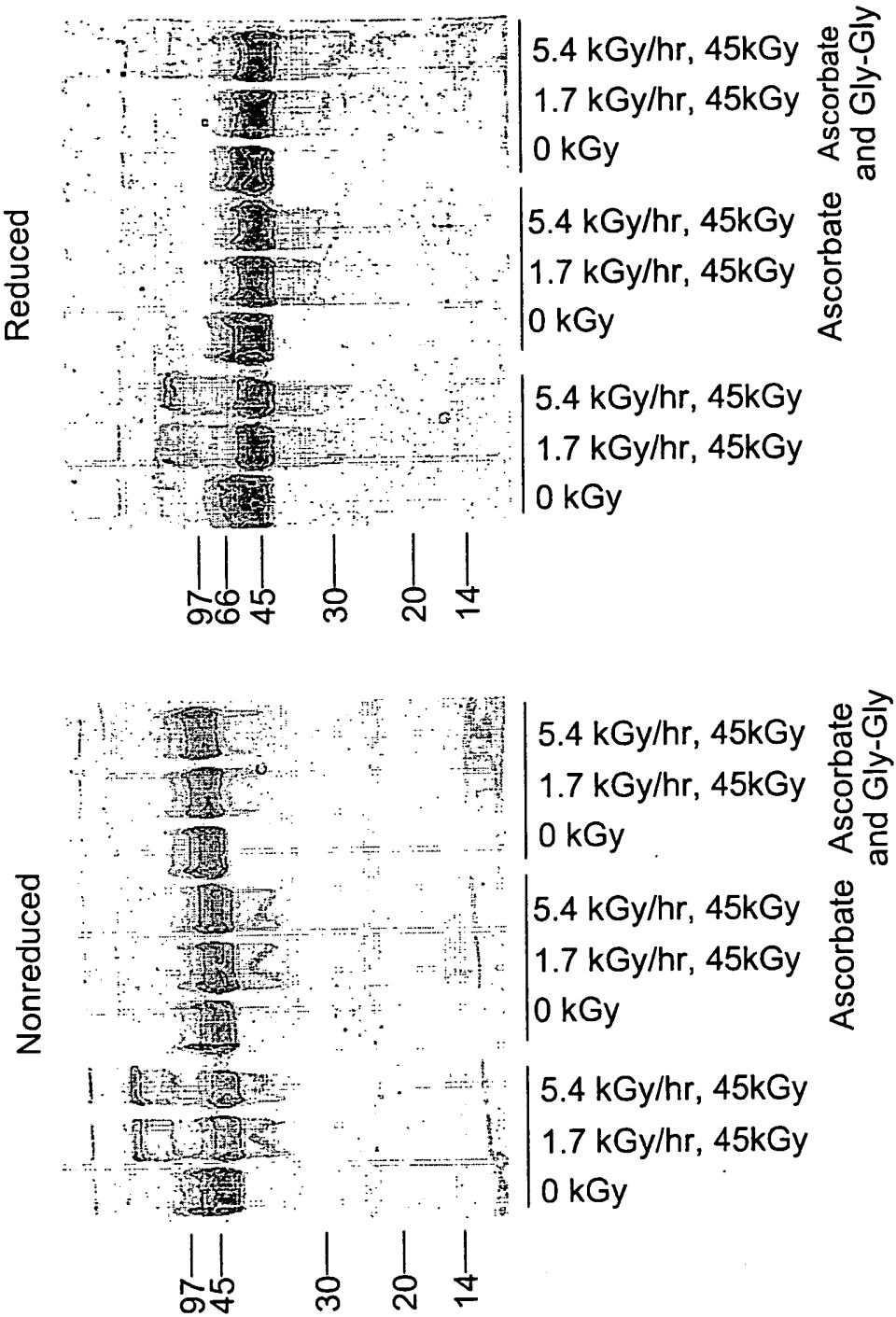


FIG. 7B

Gamma Irradiation of a Galactosidase In the Presence or Absence of Ascorbate  
Alone or in Combination with Gly-Gly

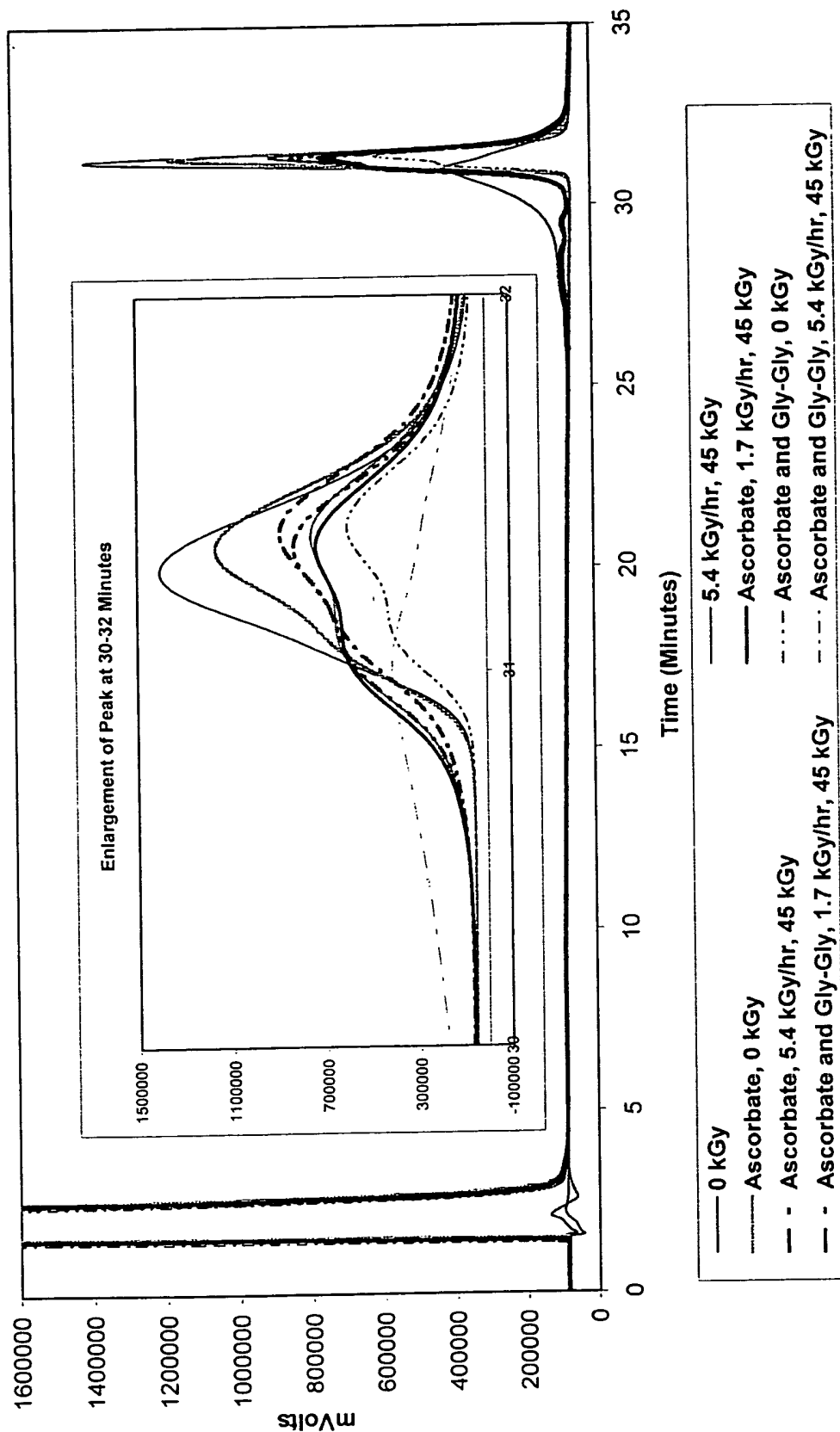


FIG. 8

Gamma Irradiation of a Lyophilized Galactosidase  
in the Absence and Presence of  
100 mM Ascorbate

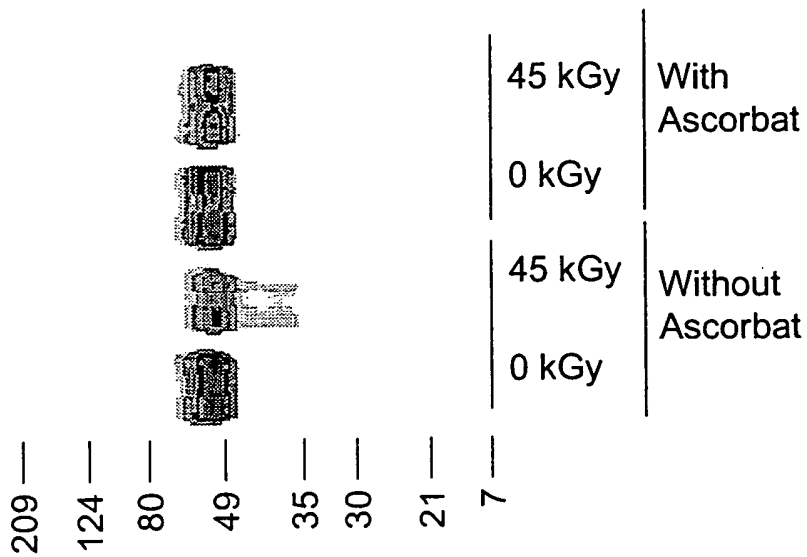


FIG. 9

# Gamma Irradiation of a Lyophilized Galactosidase In the Absence of Stabilizers

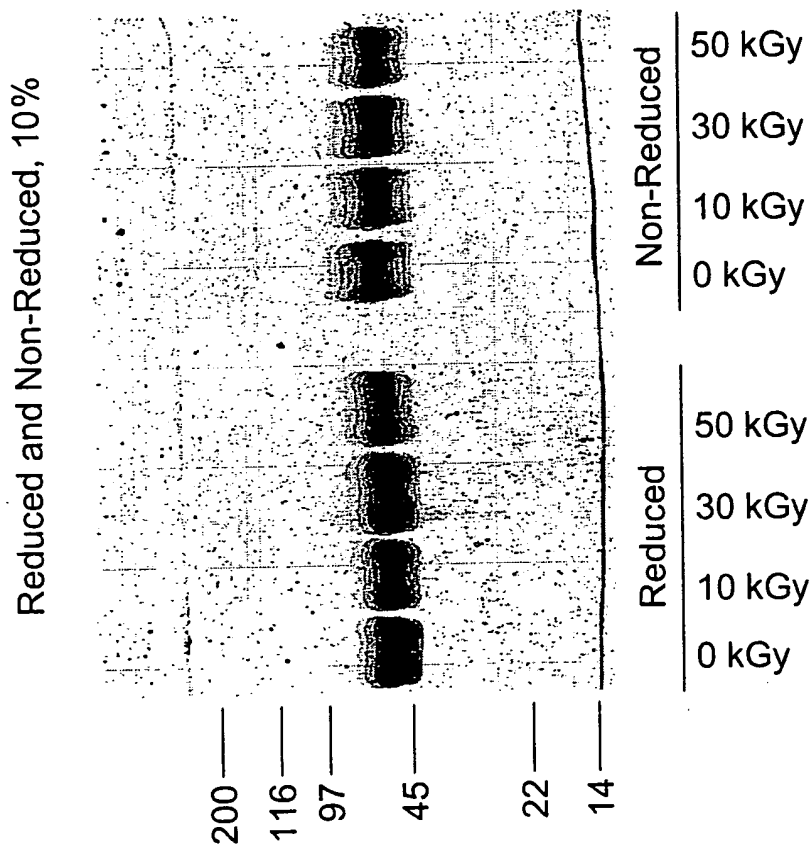


FIG. 10A



Gamma Irradiation of a Lyophilized Galactosidase  
In the Presence of 200mM Ascorbate and 200mM Gly-Gly

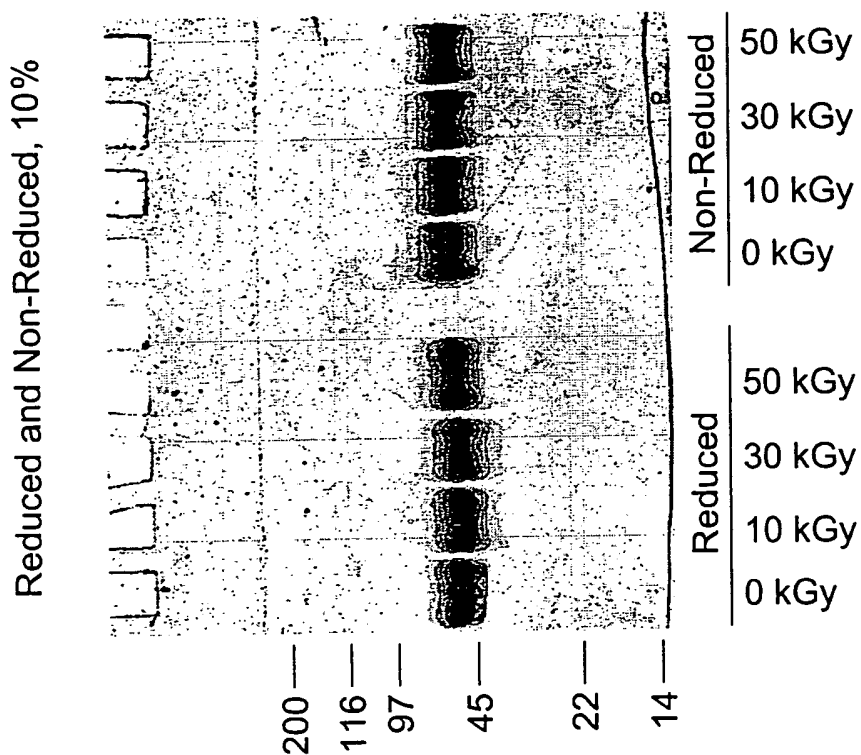


FIG. 10B

# Gamma Irradiation of a Lyophilized Galactosidase In the Presence of 200mM Ascorbate and 200mM Gly-Gly

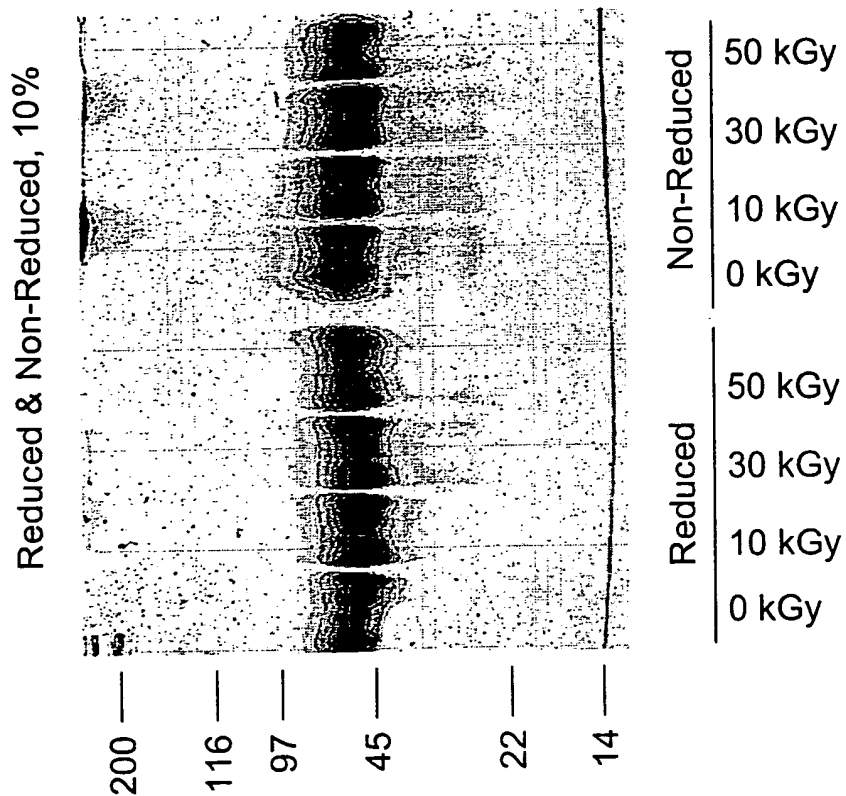


FIG. 10C



17/113

Gamma Irradiation  
of Dried Urokinase Suspended in PPG400

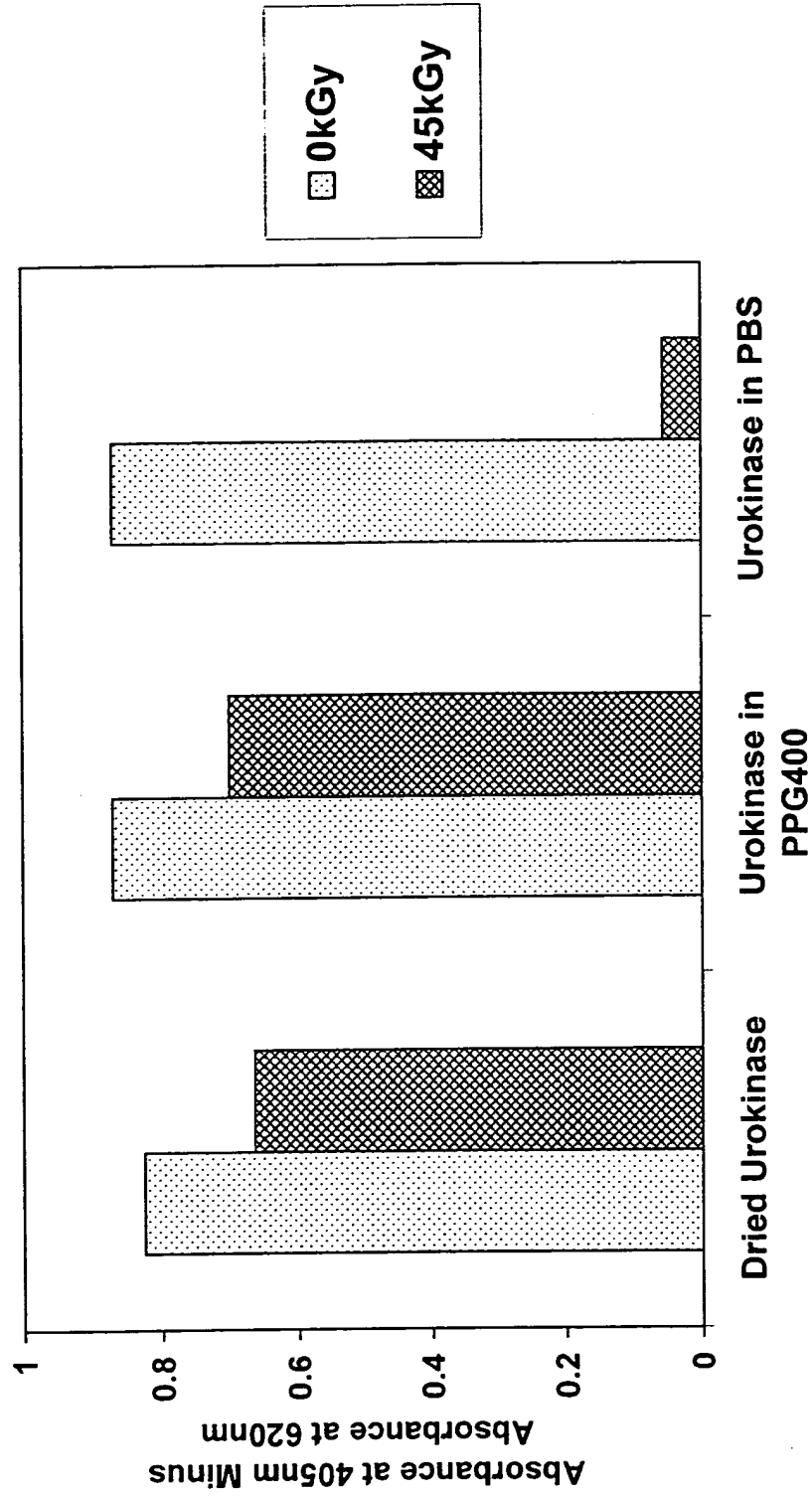


FIG. 11

Gamma Irradiation of Immobilized Monoclonal  
Antibody in the Presence of Various PPGs

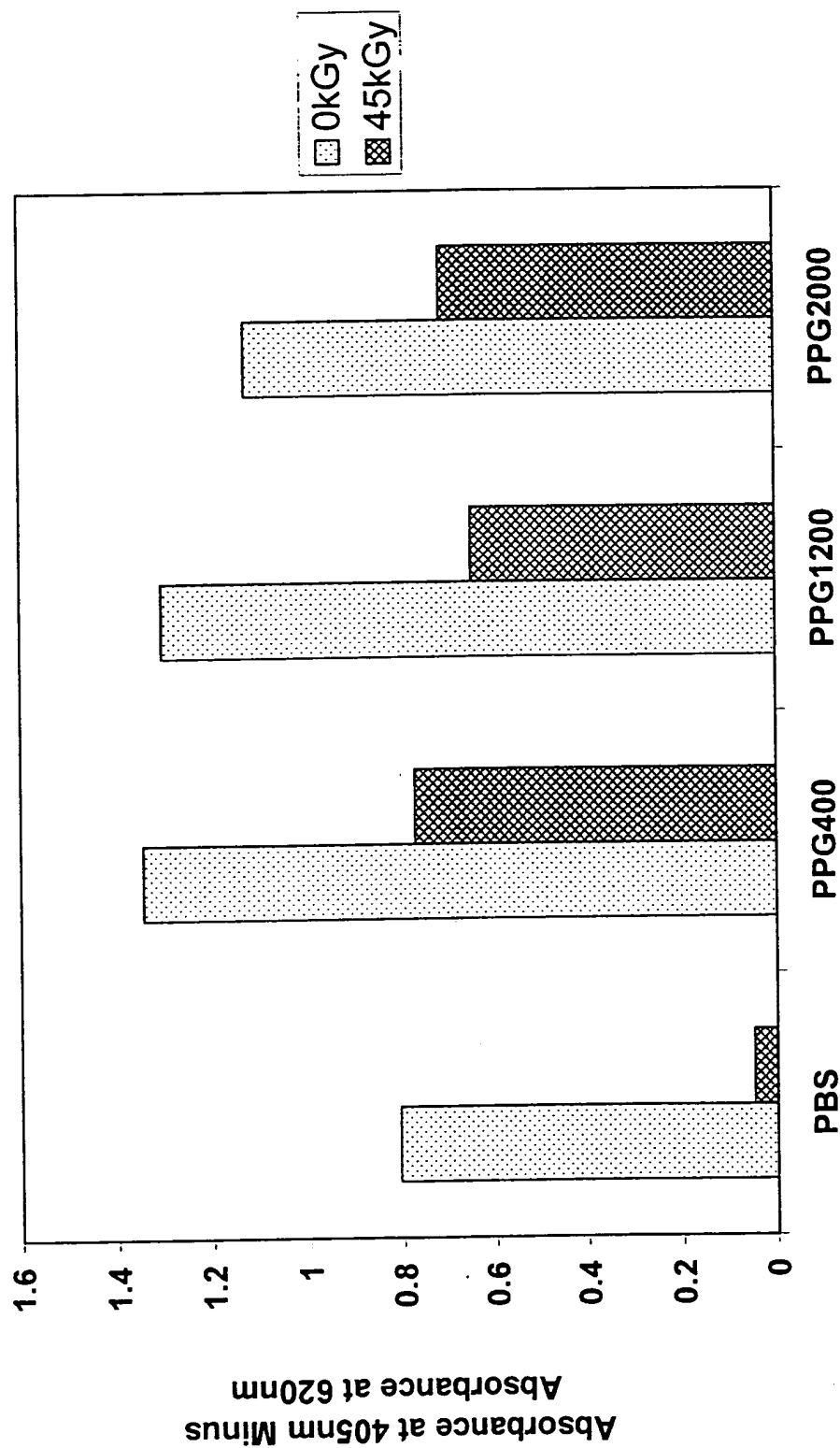


FIG. 12

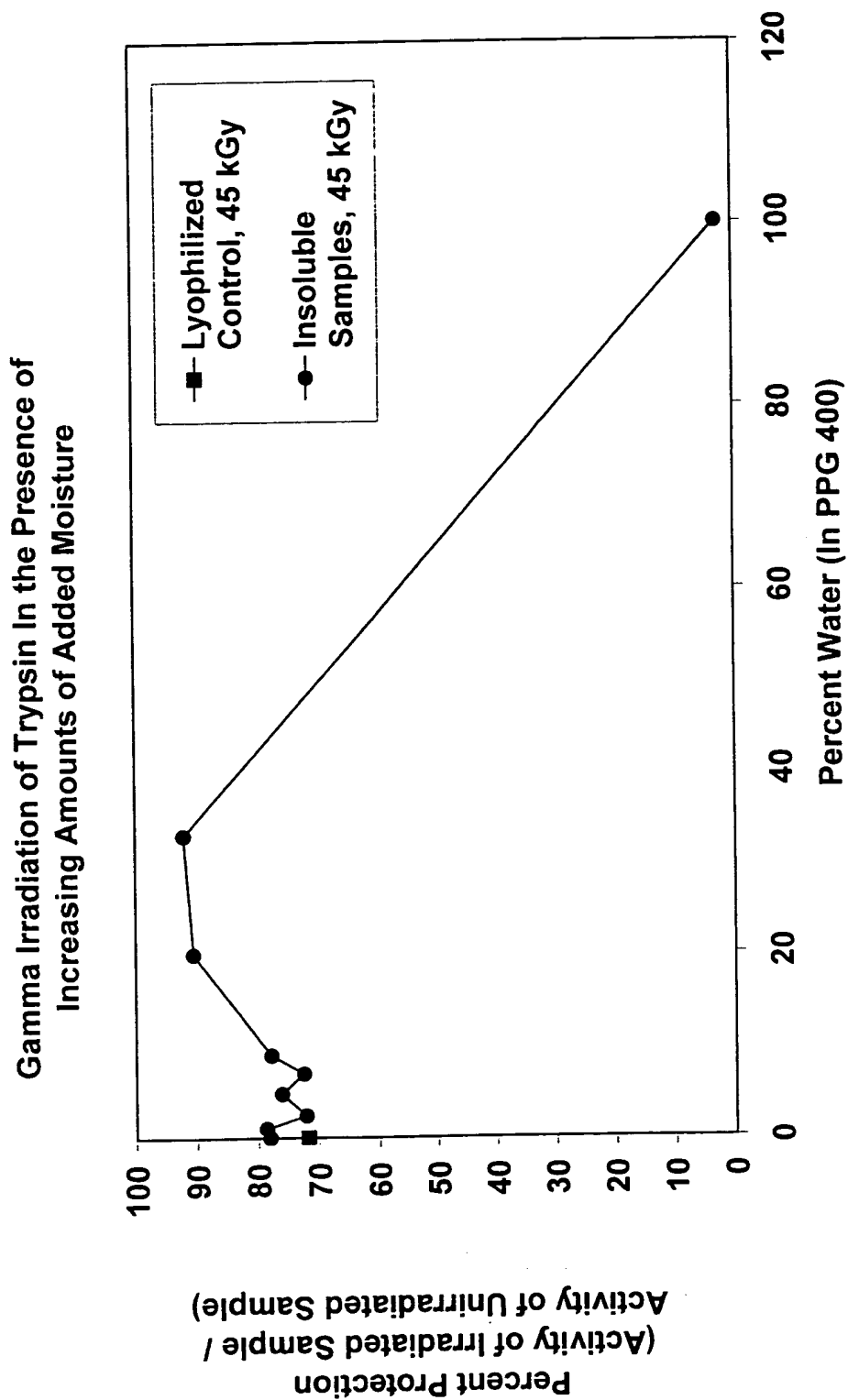


FIG. 13



20/113

Gamma Irradiation of Hydrolyzed Heart Valve  
Cusps in the Presence of PPG 400

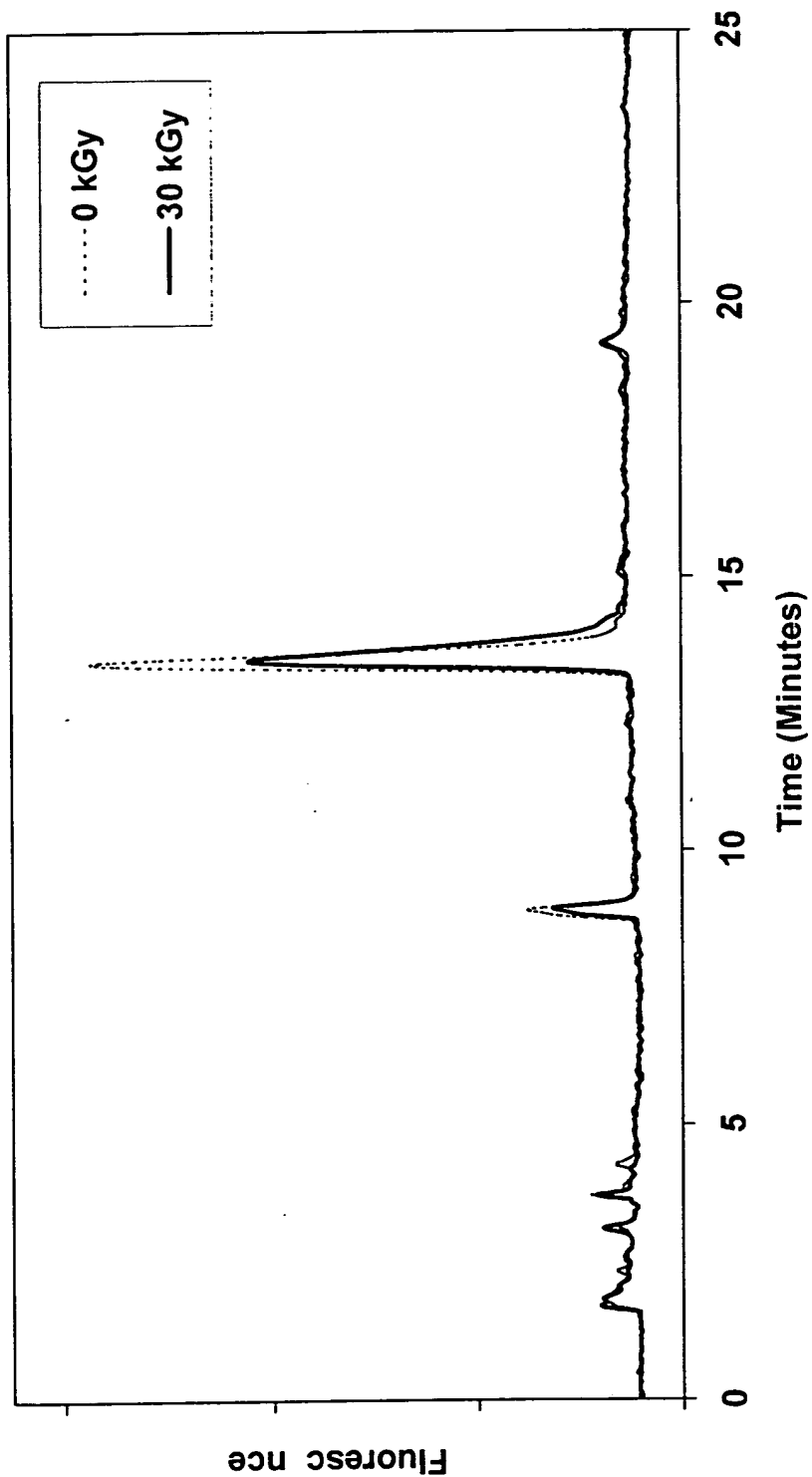


FIG. 14A

21/113

Gamma Irradiation of Hydrolyzed Heart Valve Cusps  
in the Presence of PPG 400 and 125 mM Trolox C

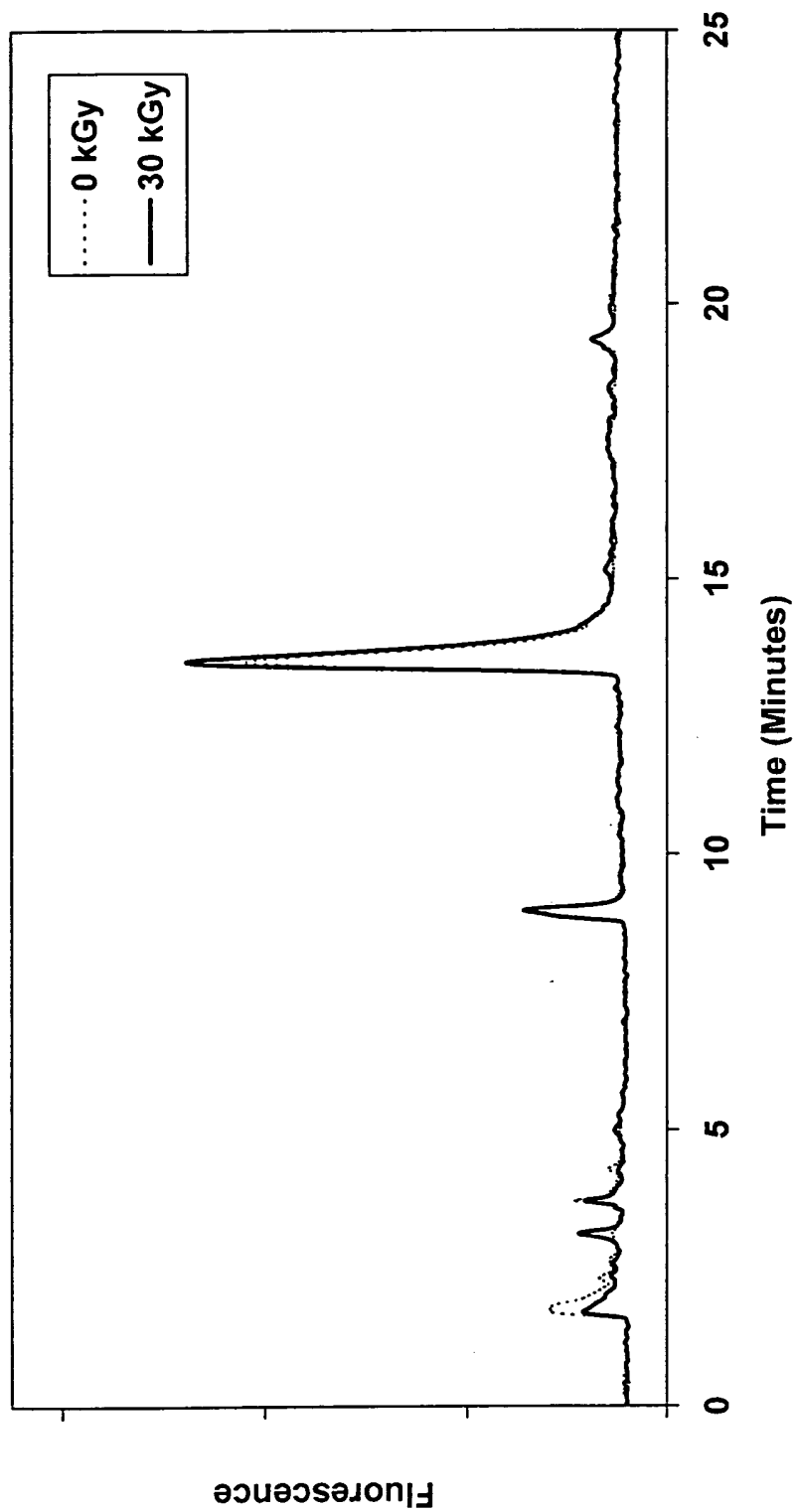


FIG. 14B

22/113

Gamma Irradiation of Hydrolyzed Heart Valve Cusps in the Presence of PPG 400  
and a Stabilizer Mixture of 62.5mM Trolox, 100mM Lipoic Acid,  
100mM Coumaric Acid, and 100mM n-Propyl Gallate

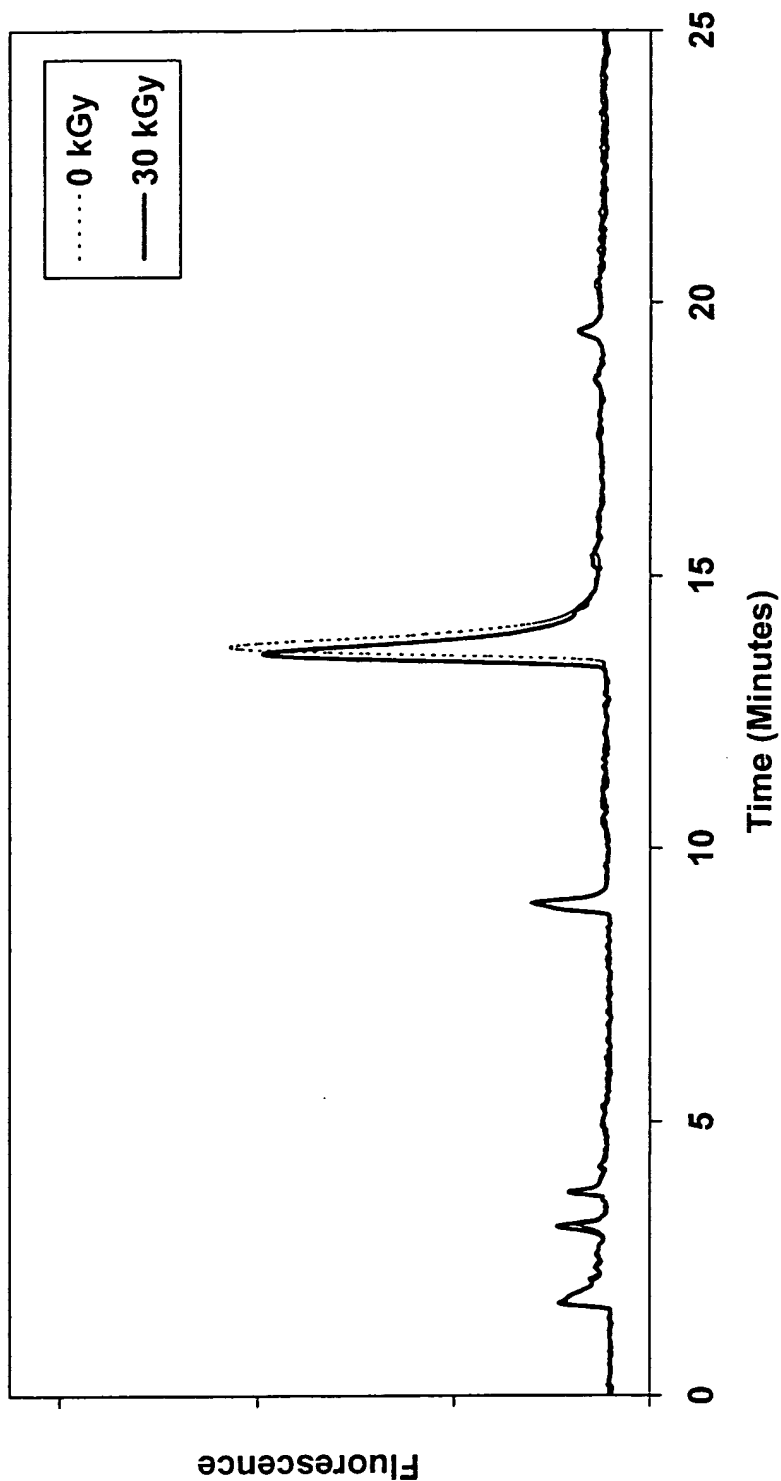


FIG. 14C



23/113

# Gamma Irradiation of Porcine Heart Valve Cusps in the Presence of PPG400 with Various Stabilizers

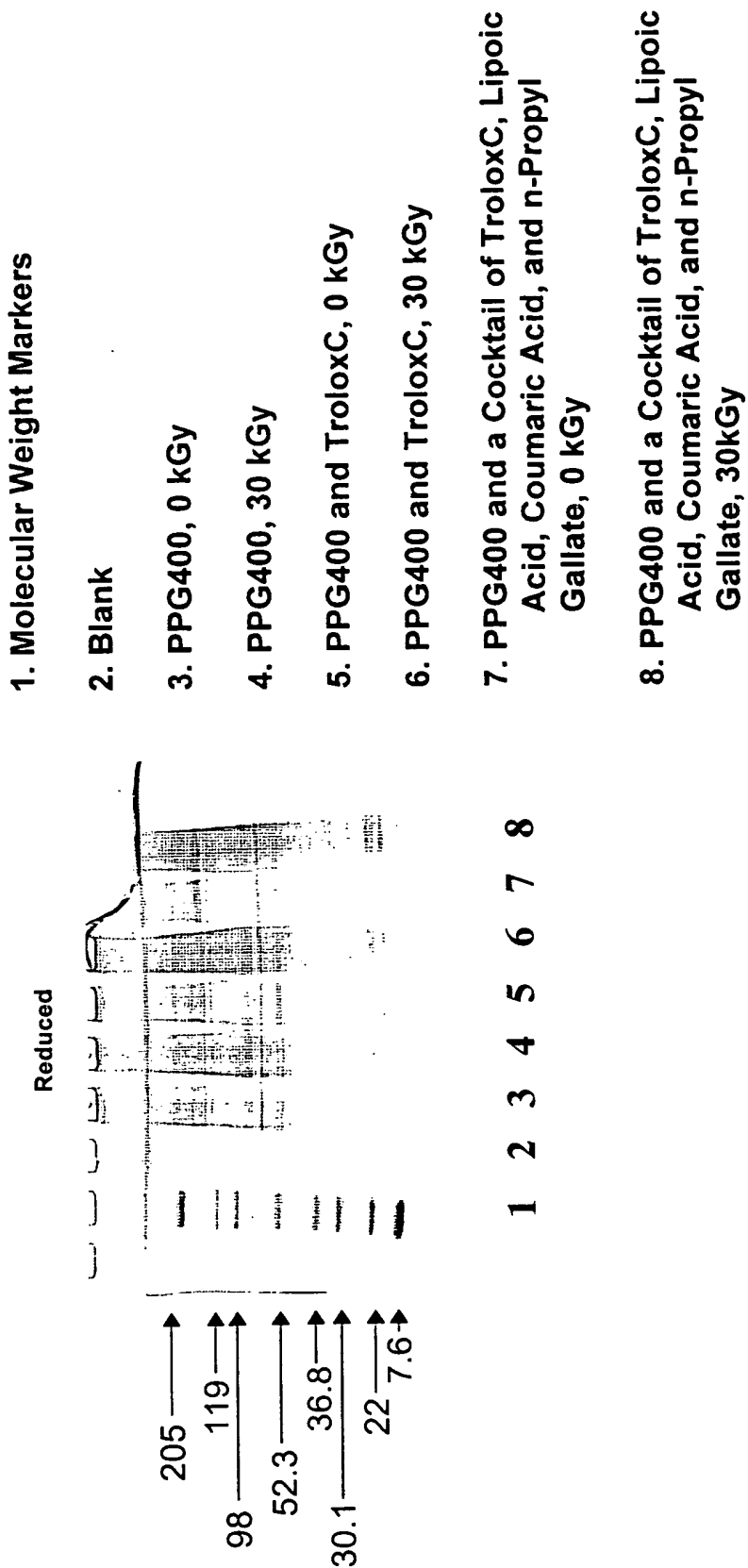


FIG. 14D



24/113

Gamma Irradiation of Hydrolyzed Heart Valve  
Cusps in the Presence of PBS

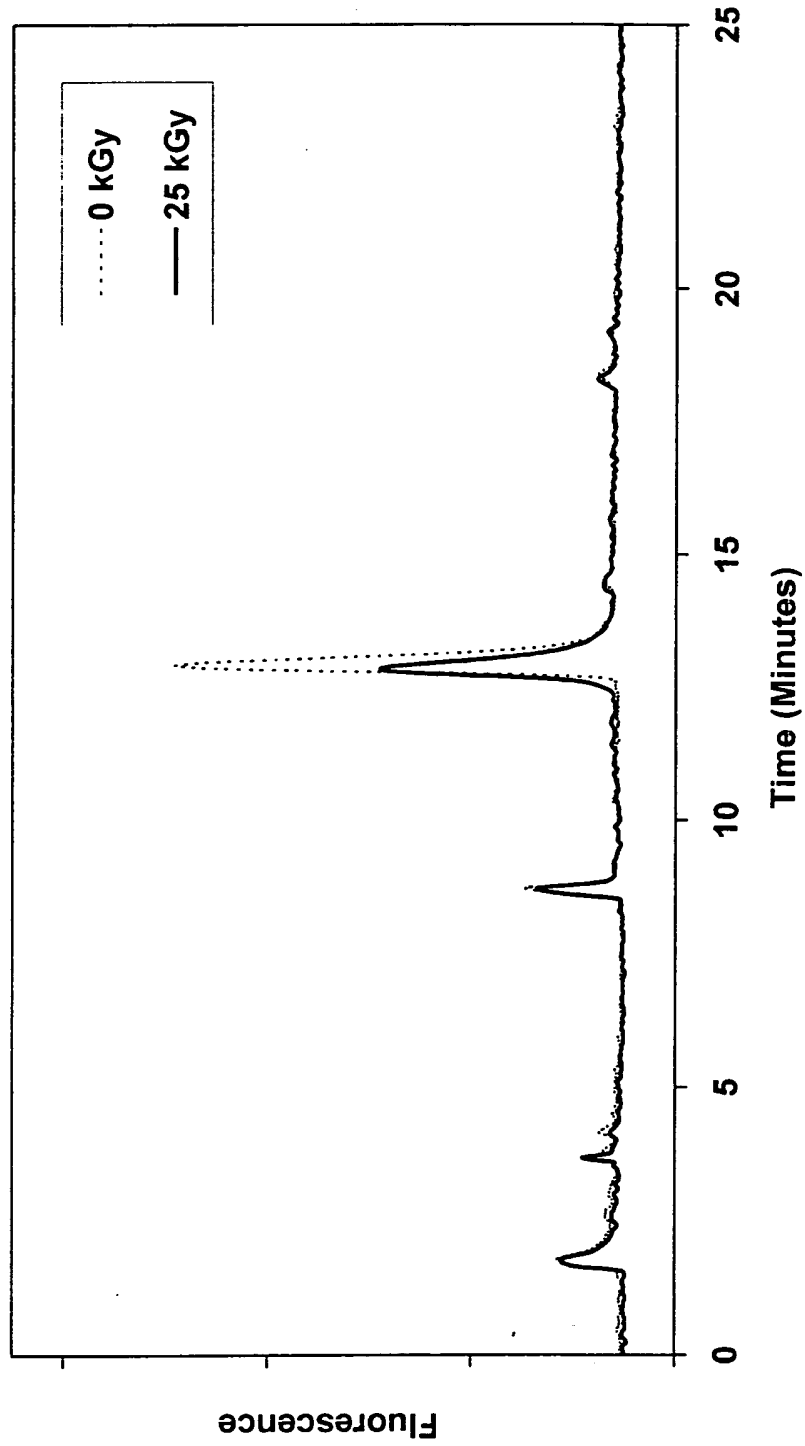


FIG. 15A





25/113

Gamma Irradiation of Hydrolyzed Heart Valve  
Cusps in the Presence of PPG 400

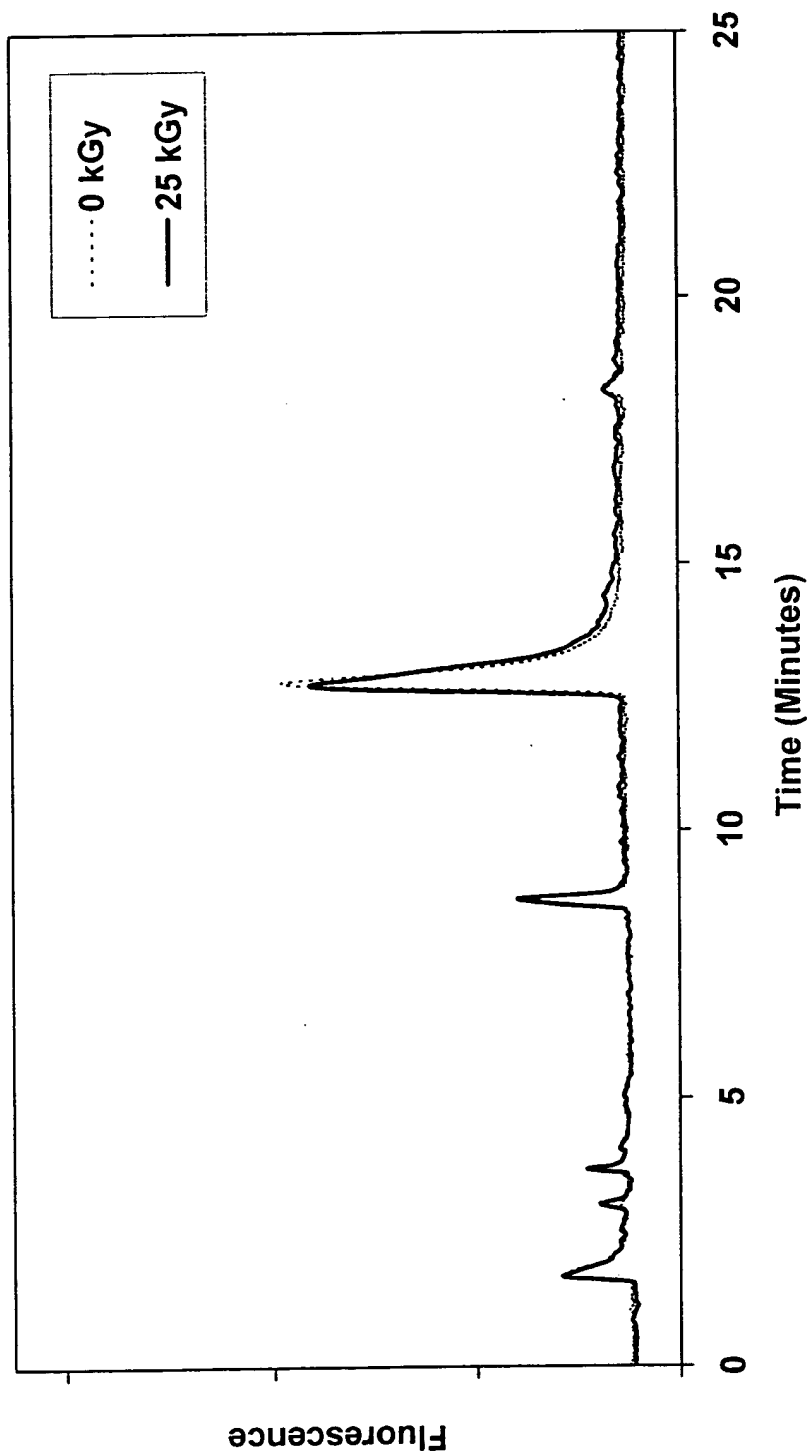


FIG. 15B



26/113

Gamma Irradiation of Hydrolyzed Heart Valve  
Cusps in the Presence of 50% DMSO

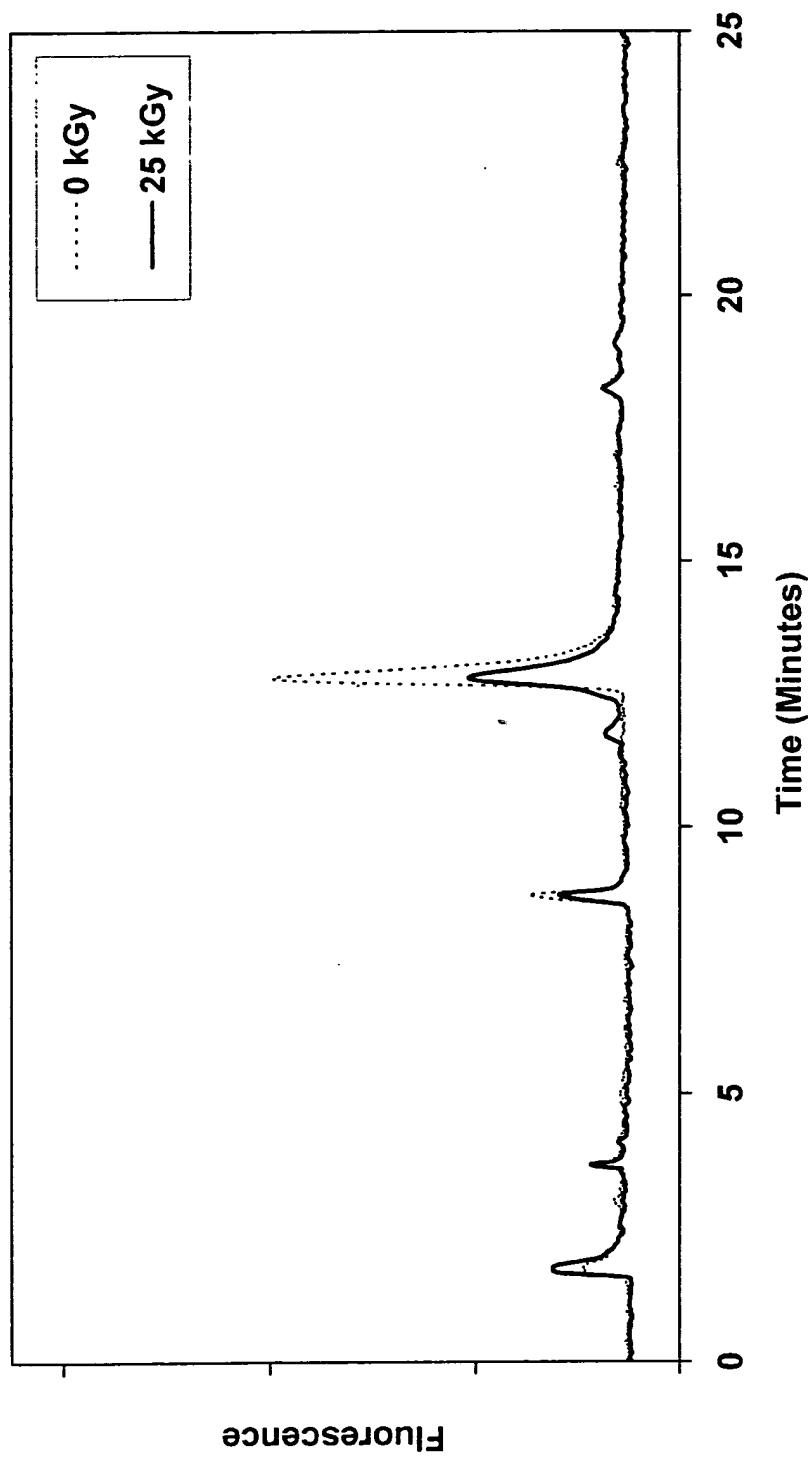


FIG. 15C



27/113

Gamma Irradiation of Hydrolyzed Heart Valve Cusps in the Presence of 50%  
DMSO and a Stabilizer Mixture of 167 mM Ascorbate, 166 mM Coumaric  
Acid, and 100 mM n-Propyl Gallate

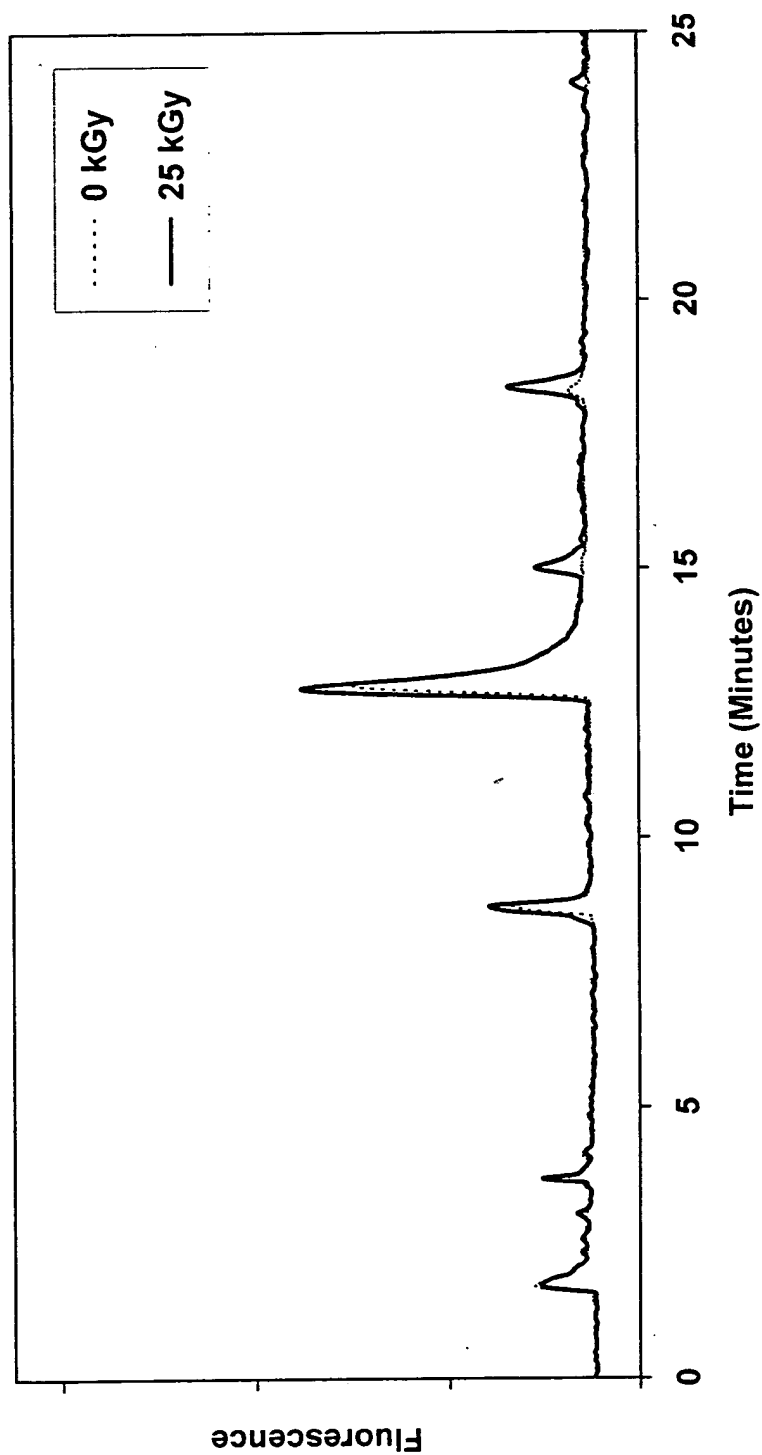


FIG. 15D

Gamma Irradiation of Porcine Heart Valve Cusps  
in the Presence of Various Solvents

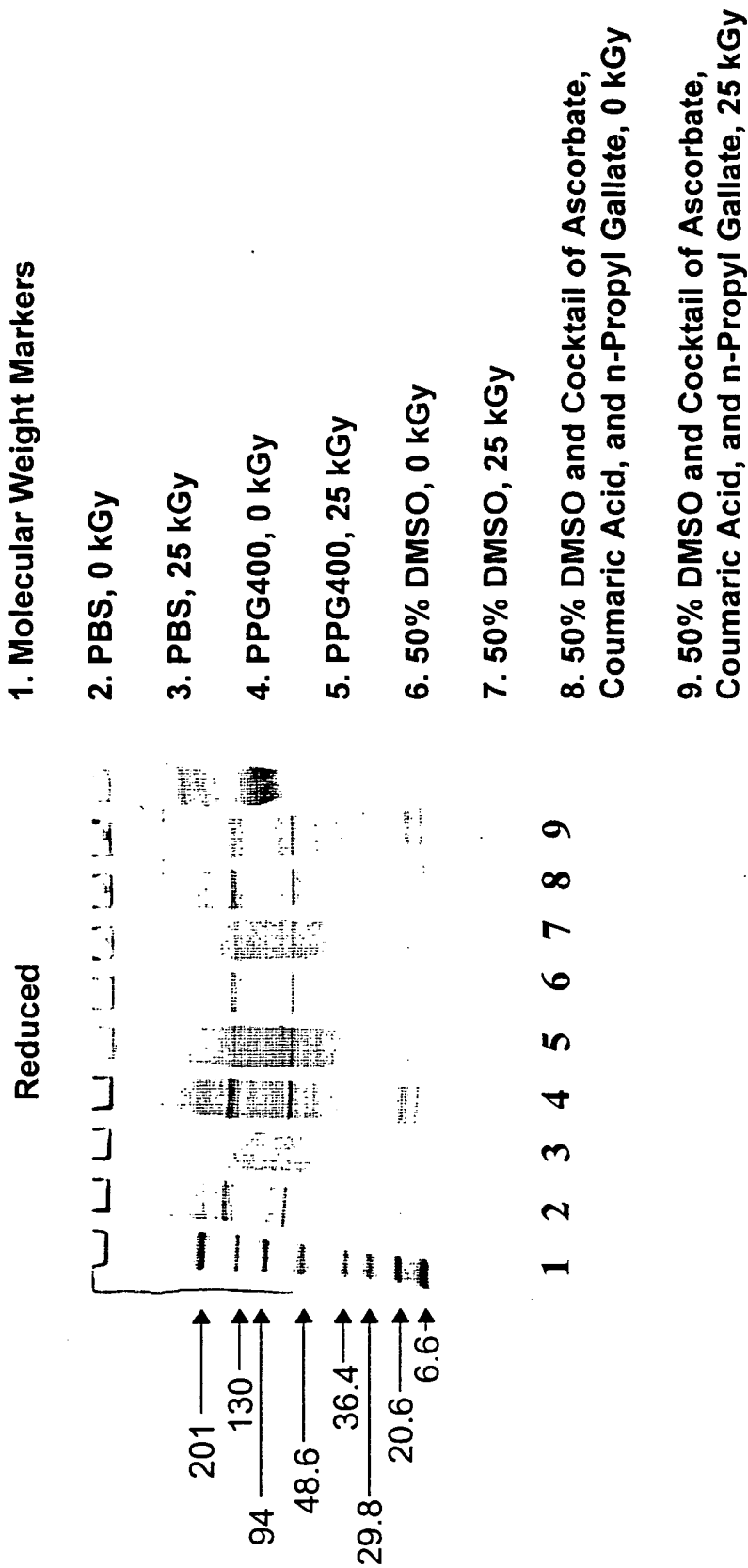


FIG. 15E



29/113

Gamma Irradiation of Hydrolyzed Heart Valve  
Cusps in the Presence of PBS

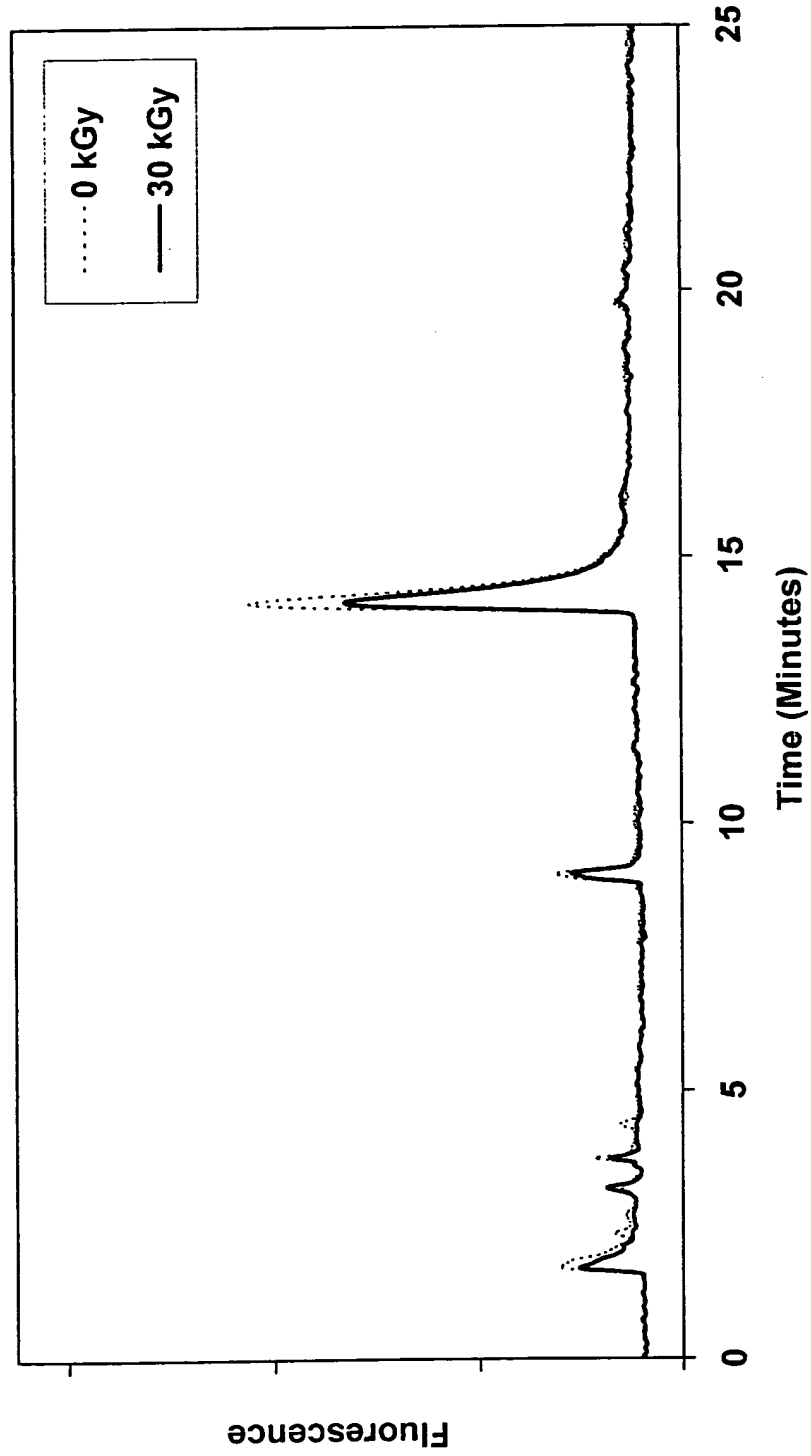


FIG. 16A



30/113

Gamma Irradiation of Hydrolyzed Heart Valve Cusps in the Presence of a  
Cryopreservative (Containing Approximately 20% DMSO)

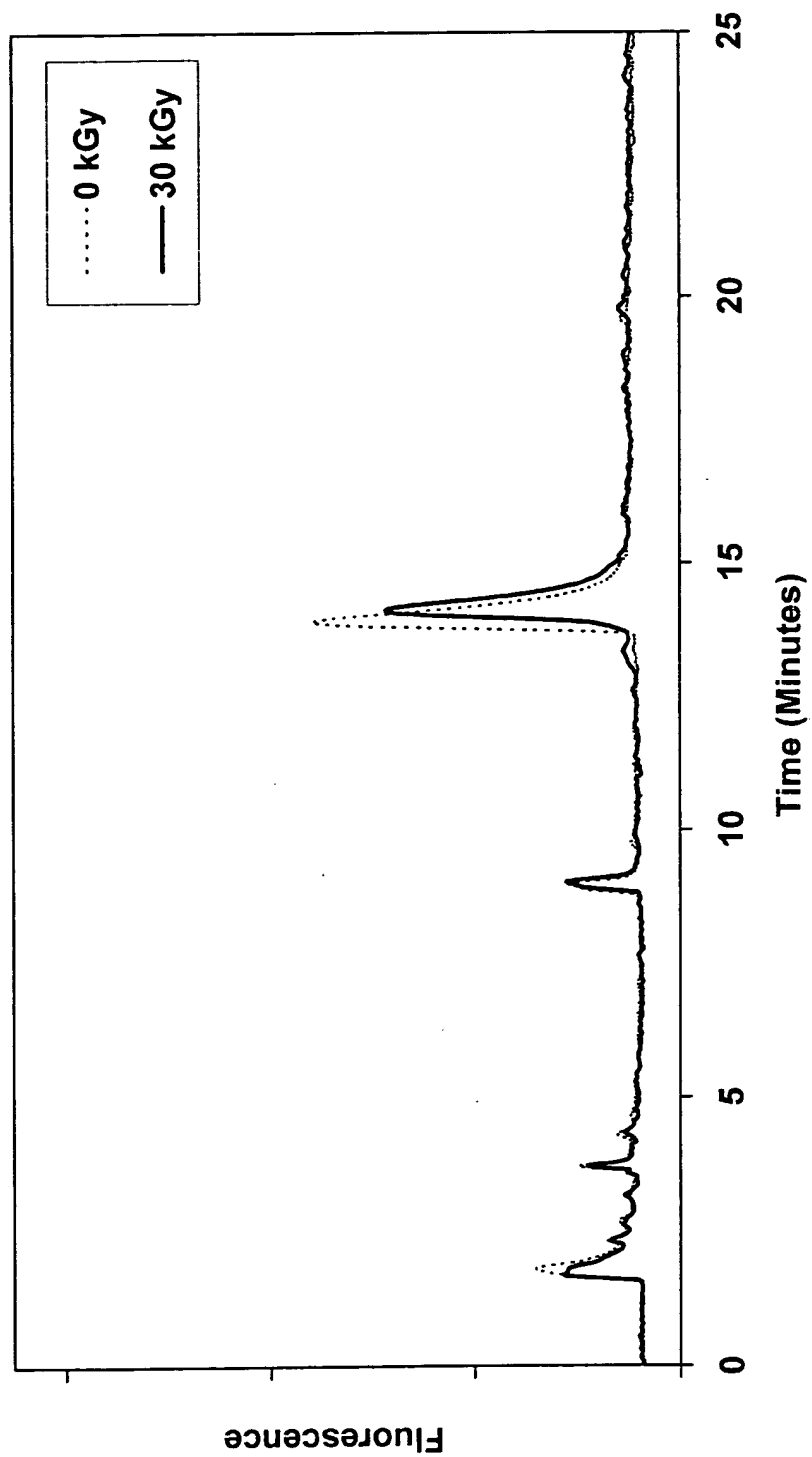


FIG. 16B



31/113

Gamma Irradiation of Hydrolyzed Heart Valve  
Cusps in the Presence of 50% DMSO

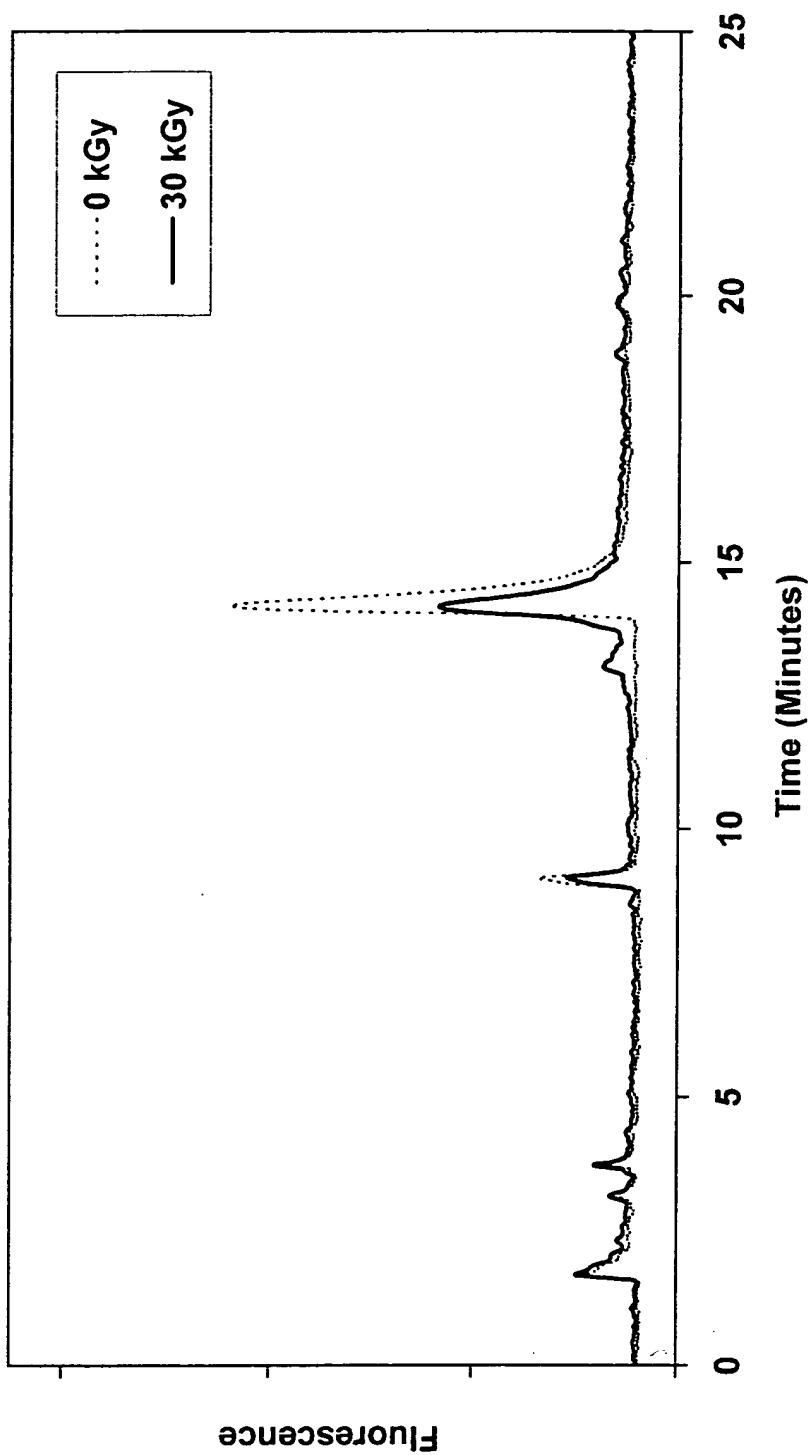


FIG. 16C



32/113

Gamma Irradiation of Hydrolyzed Heart Valve Cusps in the  
Presence of 50% DMSO and Ascorbate

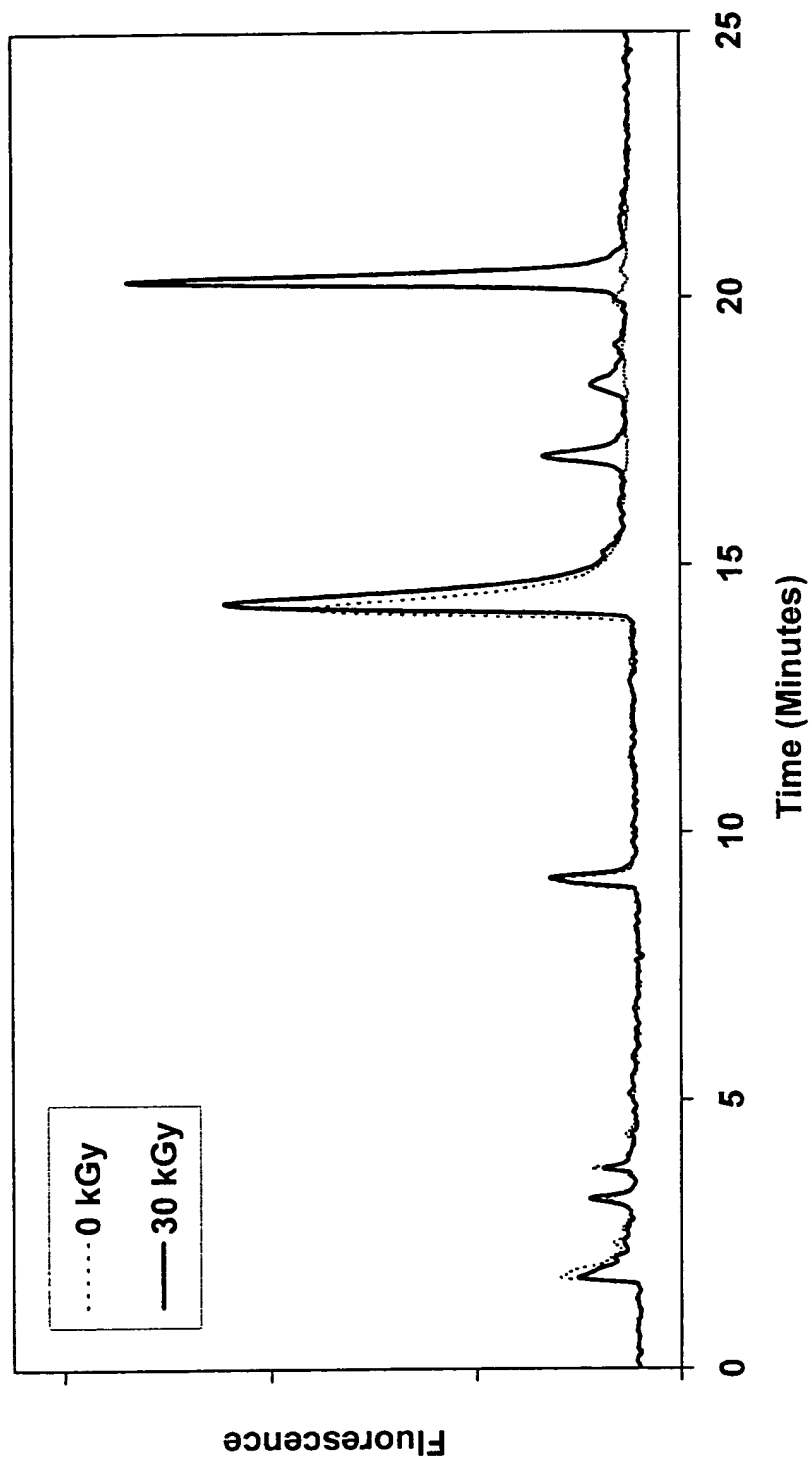


FIG. 16D



# Gamma Irradiation of Porcine Heart Valve Cusps in the Presence of Various Solvents

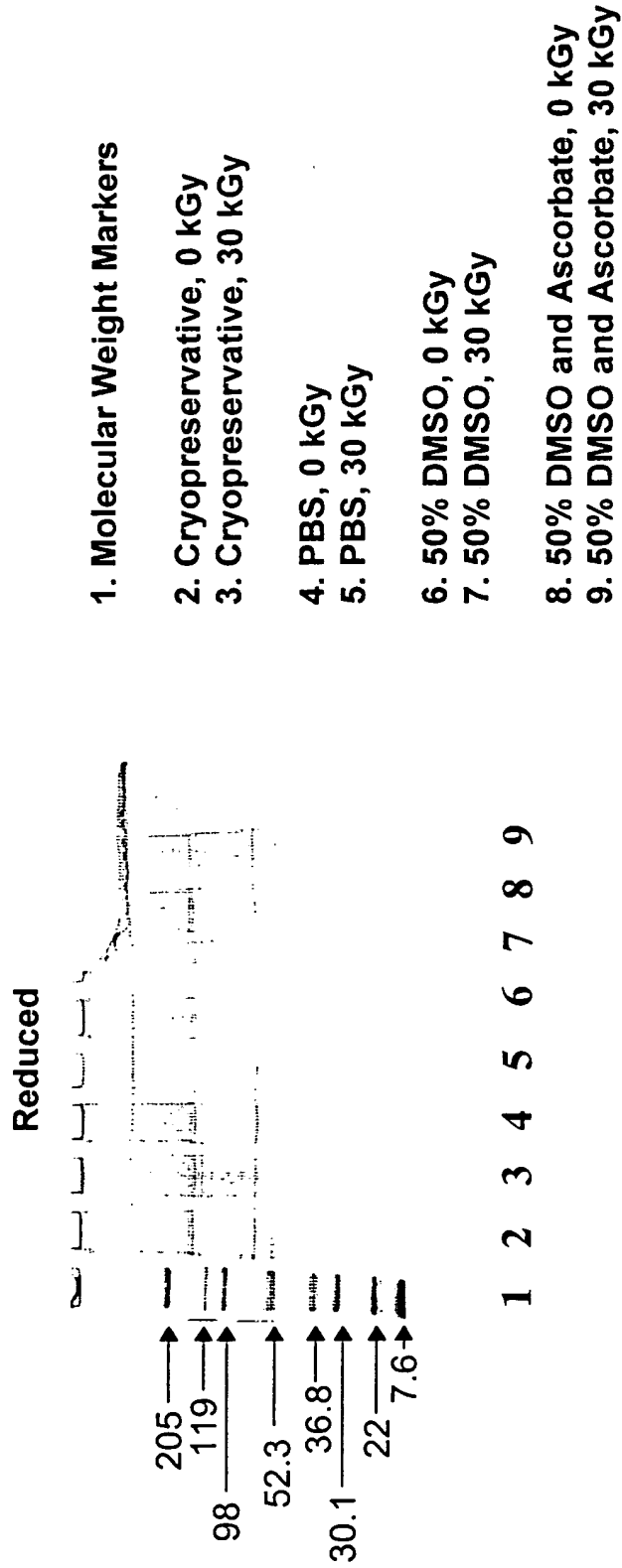


FIG. 16E



34/113

Gamma Irradiation of Hydrolyzed Heart Valve Cusps  
in the Presence of PBS

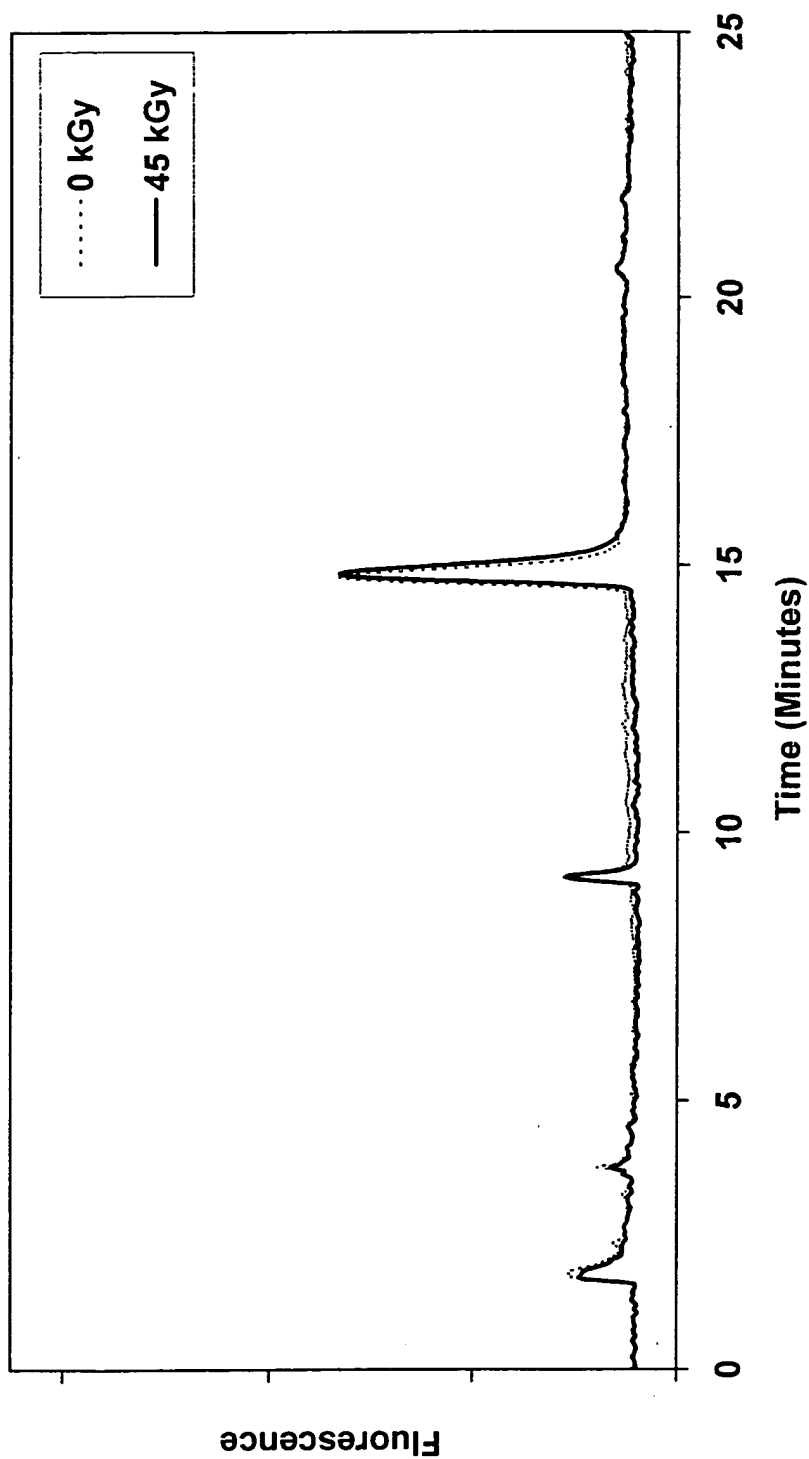


FIG. 17A

Gamma Irradiation of Hydrolyzed Heart Valve Cusps  
in the Presence of PBS and Ascorbate

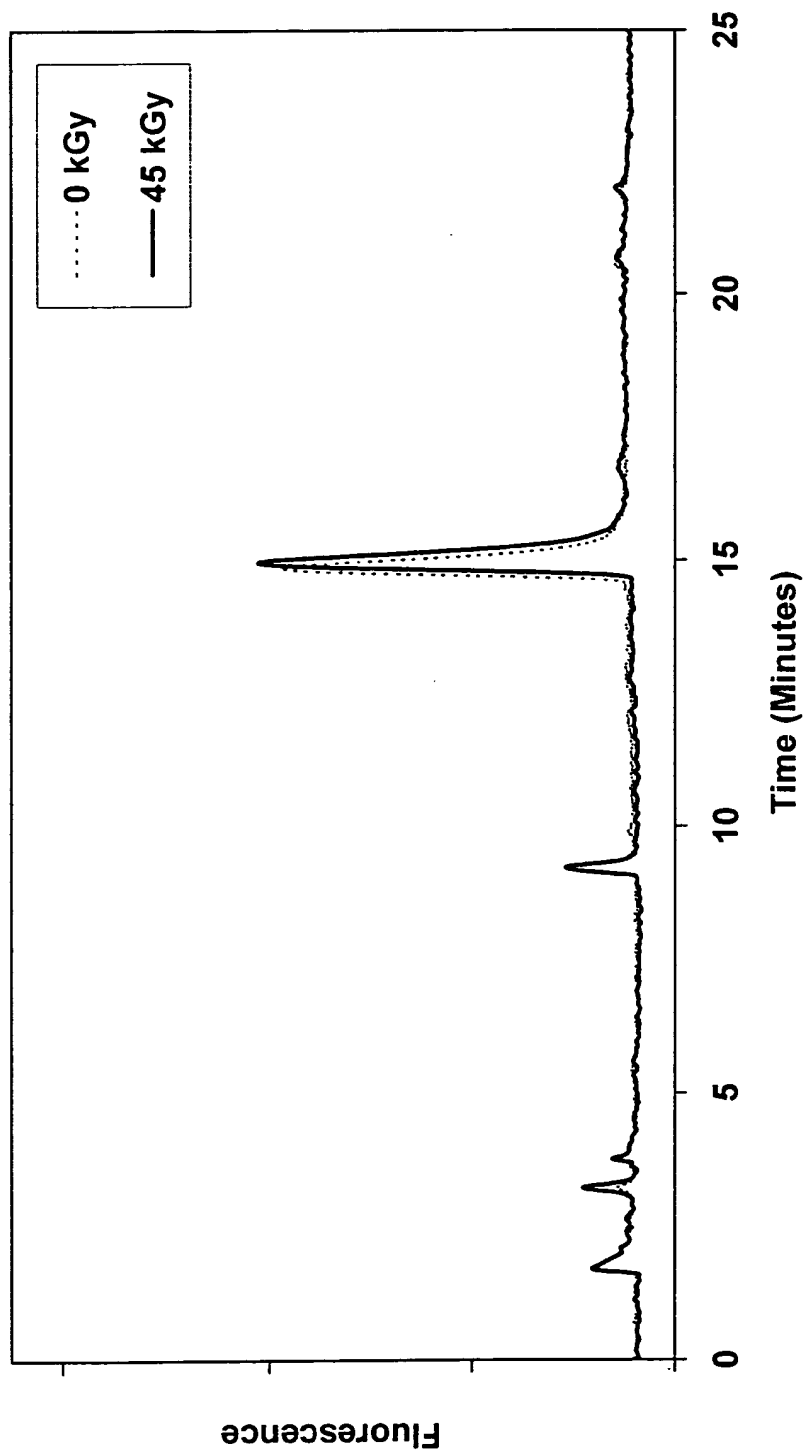


FIG. 17B



36/113

Gamma Irradiation of Hydrolyzed Heart Valve Cusps  
in the Presence of PPG 400

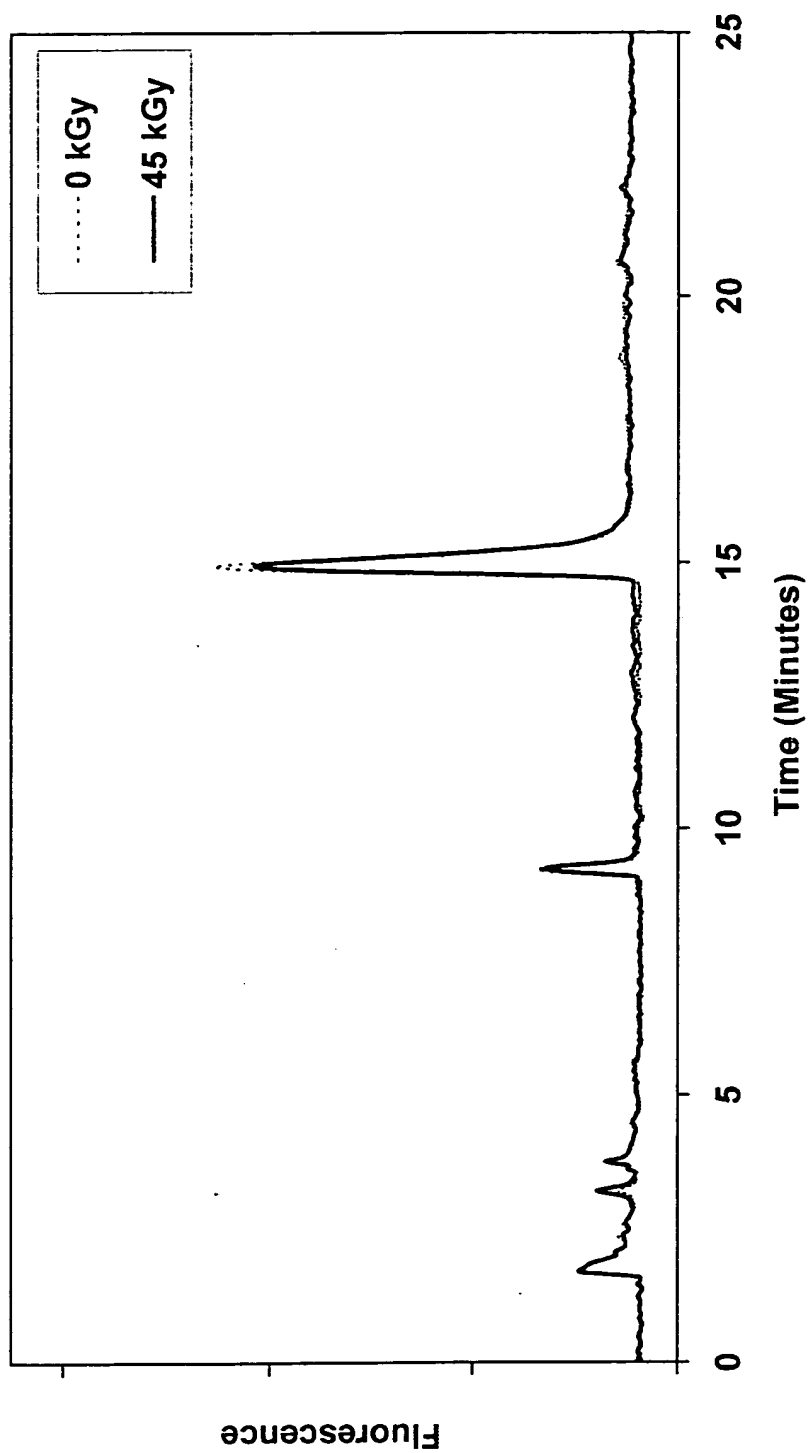


FIG. 17C



37/113

Gamma Irradiation of Hydrolyzed Heart Valve Cusps Dehydrated with PPG  
400 and Rehydrated in the Presence of PBS and Ascorbate

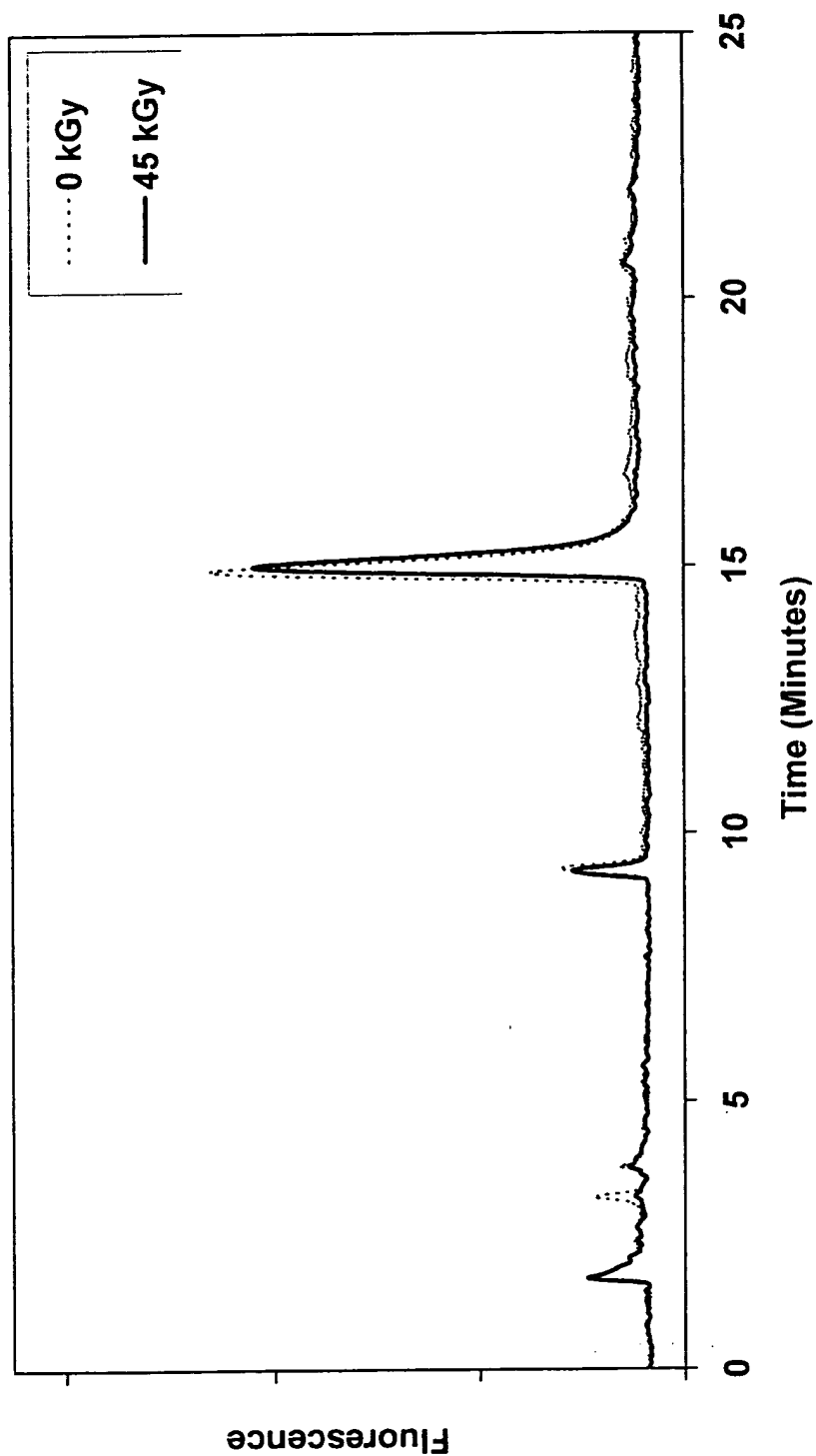


FIG. 17D



38/113

Gamma Irradiation of Hydrolyzed Heart Valve Cusps  
in the Presence of 50% DMSO

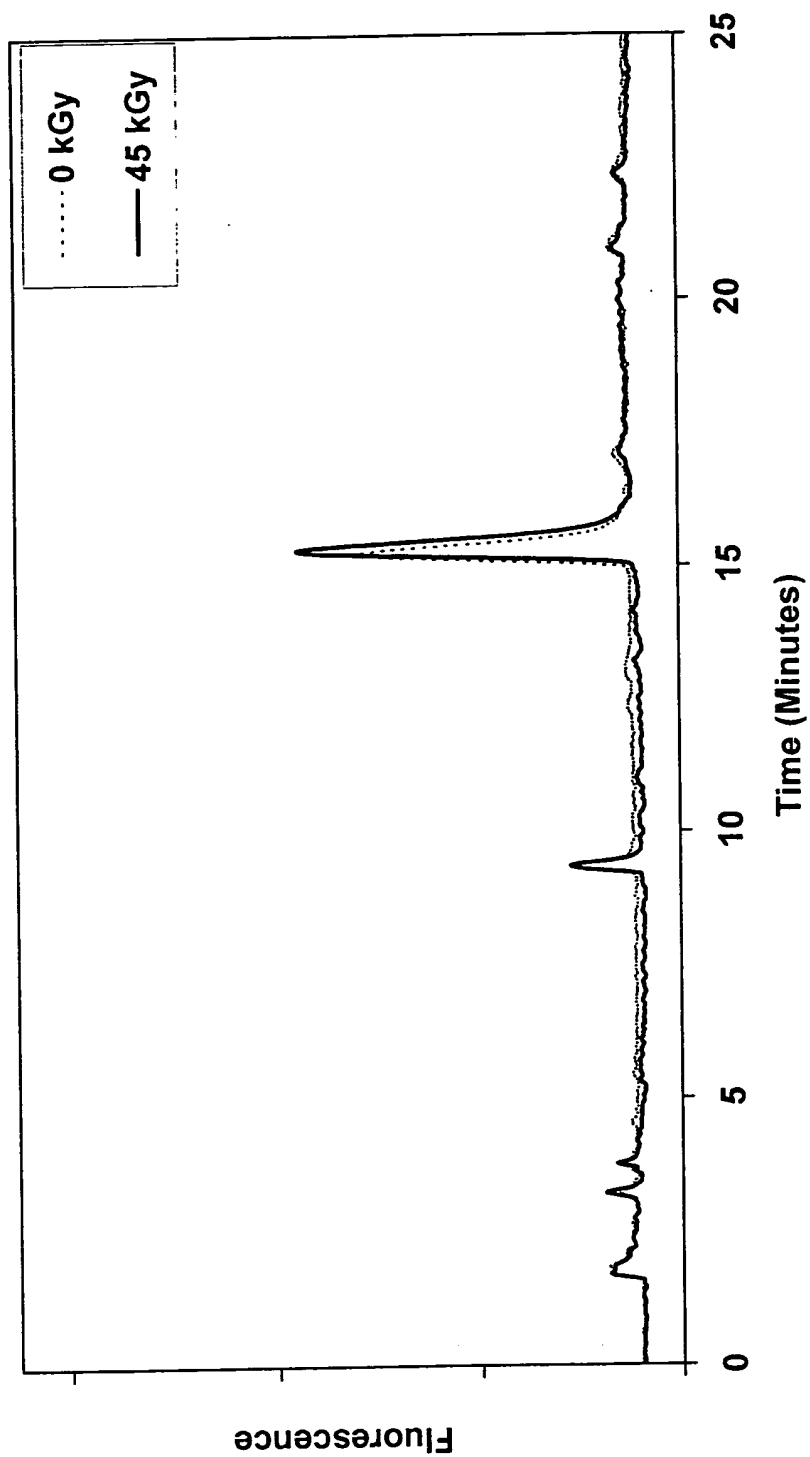


FIG. 17E

Gamma Irradiation of Hydrolyzed Heart Valve Cusps  
in the Presence of 50% DMSO and Ascorbate

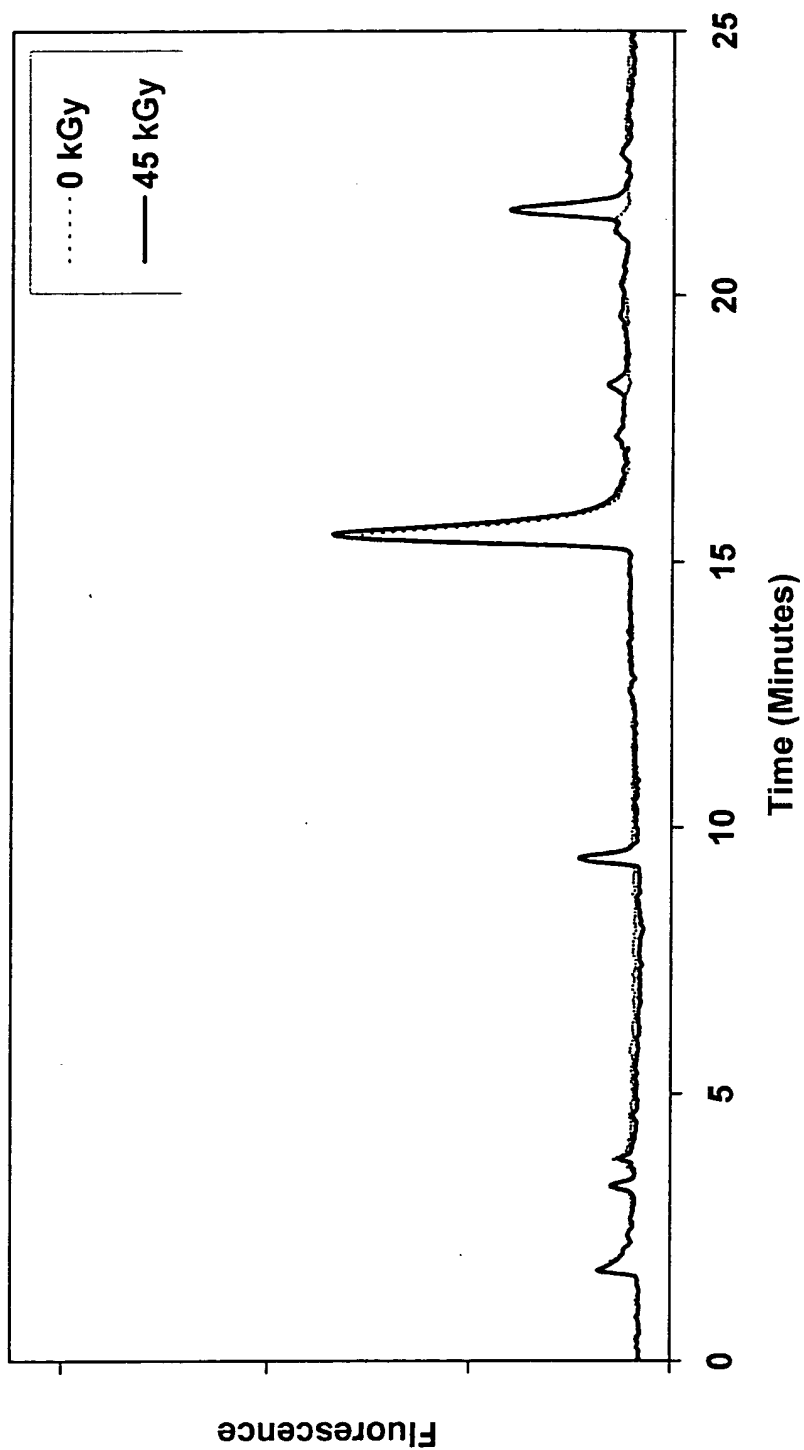


FIG. 17F

# Gamma Irradiation of Porcine Heart Valve Cusps in the Presence of Various Solvents

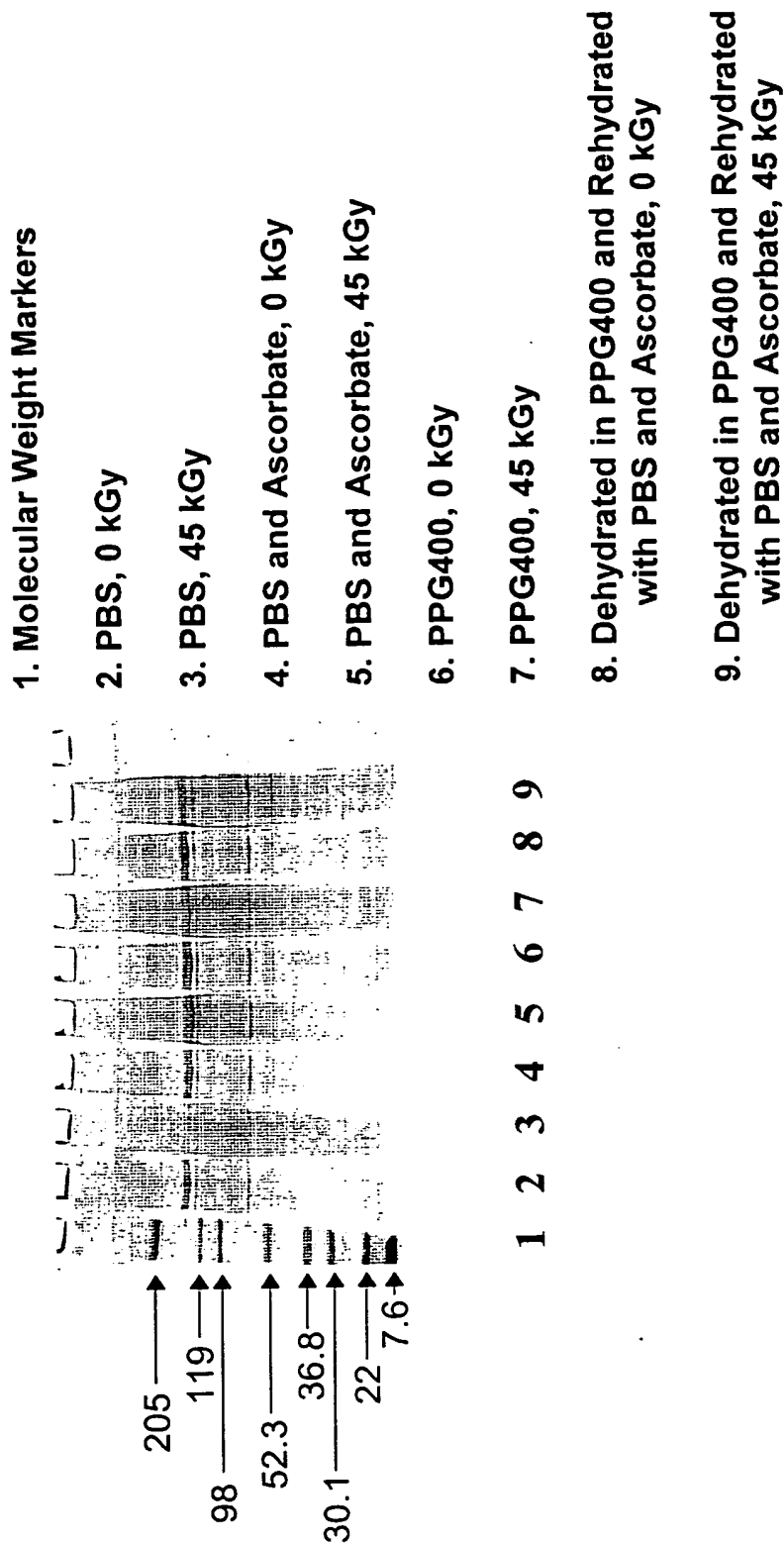


FIG. 17G



# Gamma Irradiation of Porcine Heart Valve Cusps in the Presence of Various Solvents

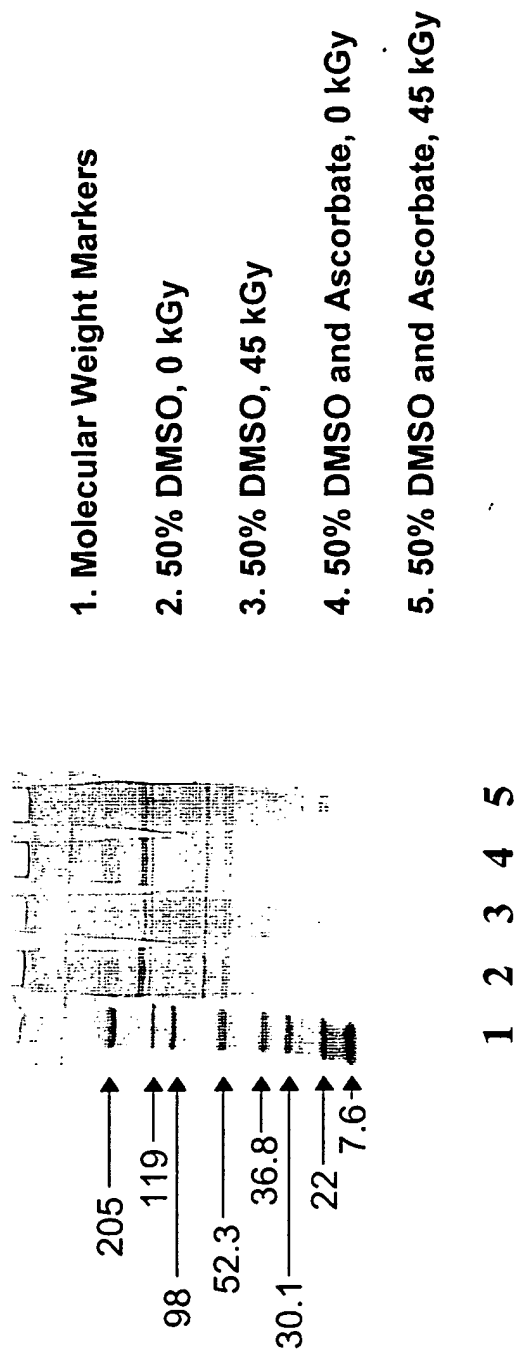


FIG. 17H

Gamma Irradiation of Freeze-Dried Anti-Insulin Monoclonal Antibody in the Presence or Absence of 20 mM Gly-Gly (1% HSA)

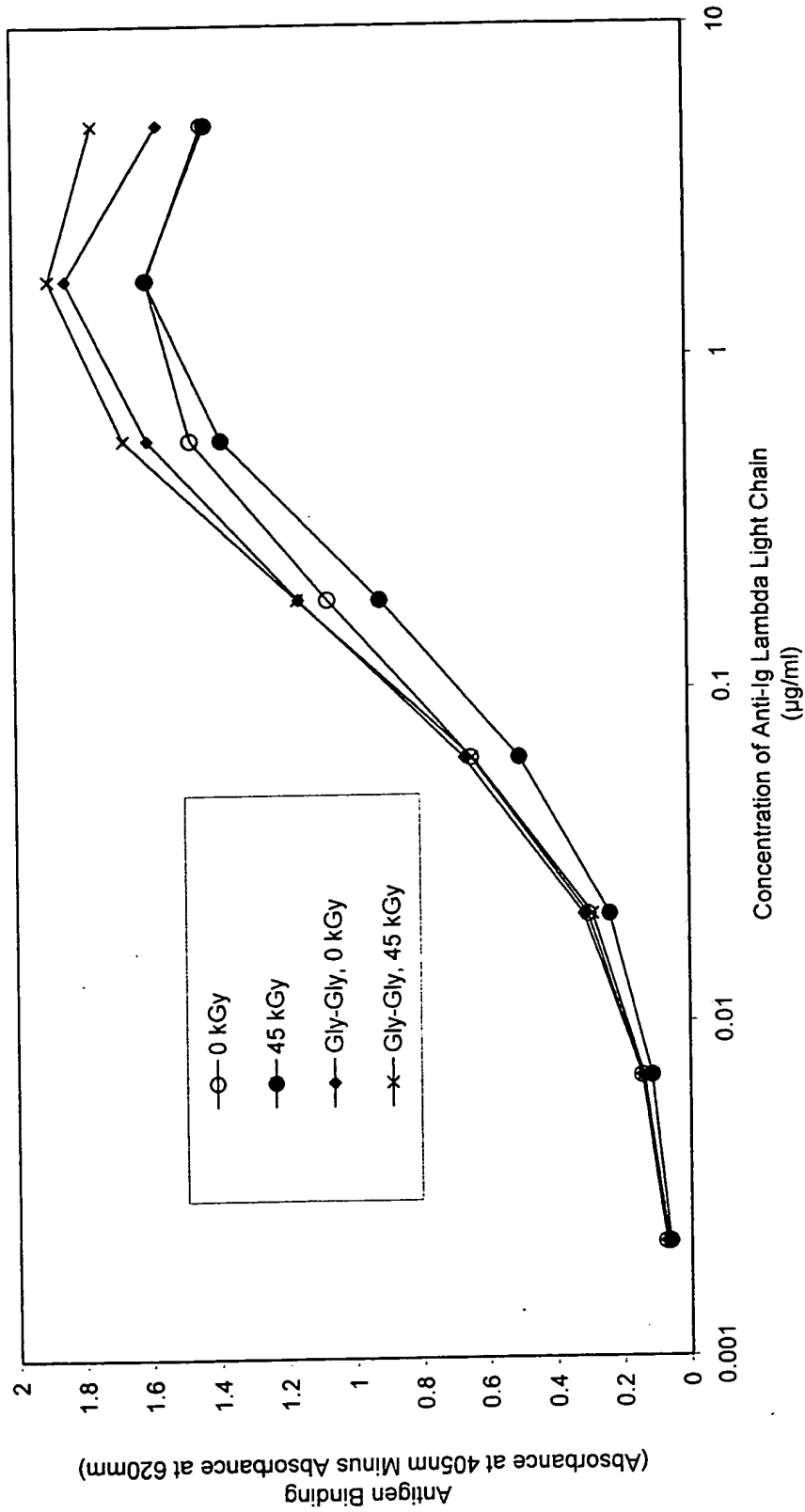


FIG. 18A

Gamma Irradiation of Freeze-Dried Anti-Human Ig, Lambda Light Chain, in the  
Presence or Absence of 20 mM Gly-Gly

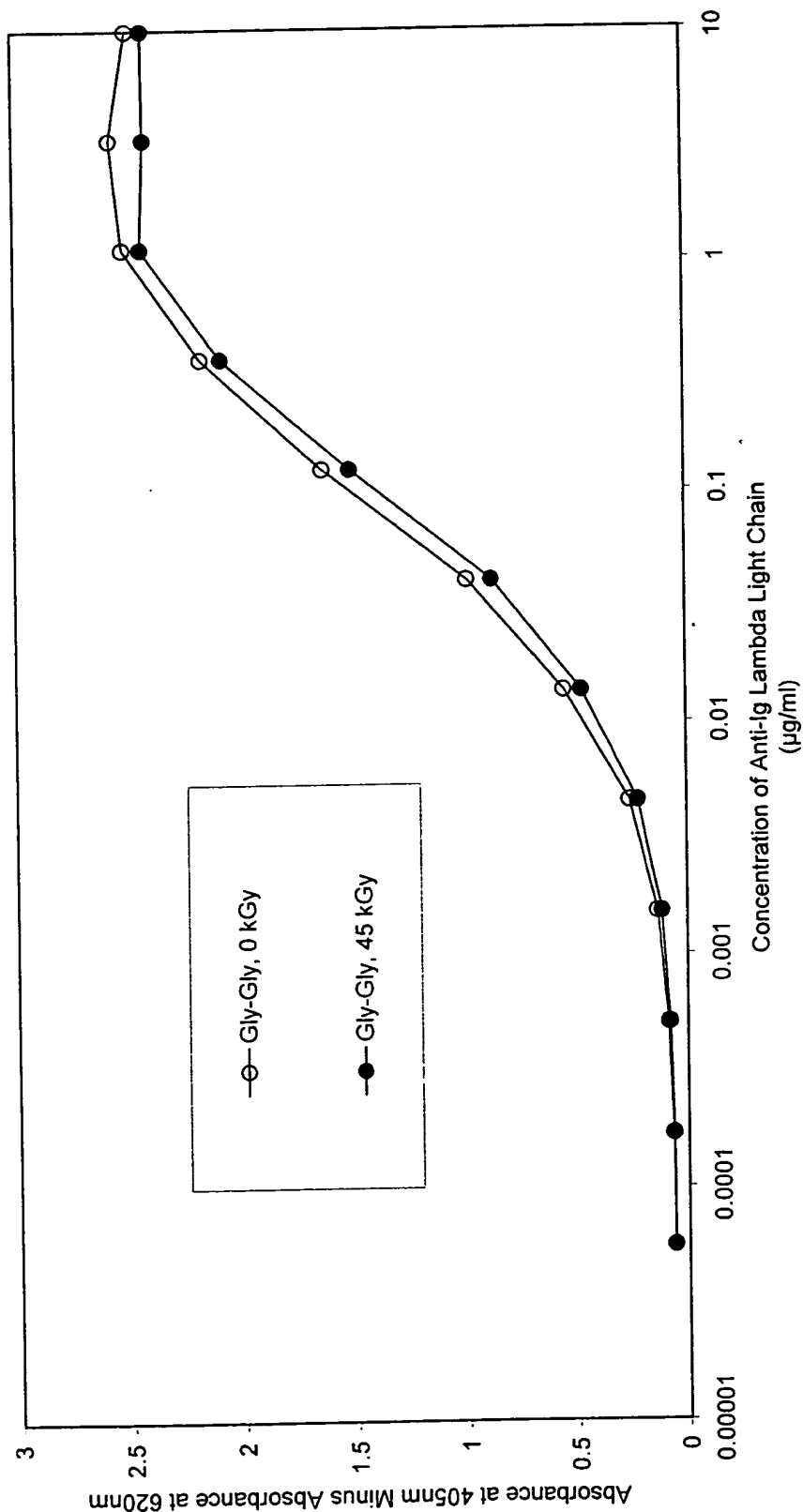


FIG. 18B



44/113

Gamma Irradiation of Freeze-Dried Anti-Human Ig, Lambda Light Chain, in the Presence or Absence of 20mM Ascorbate and 20mM Gly-Gly

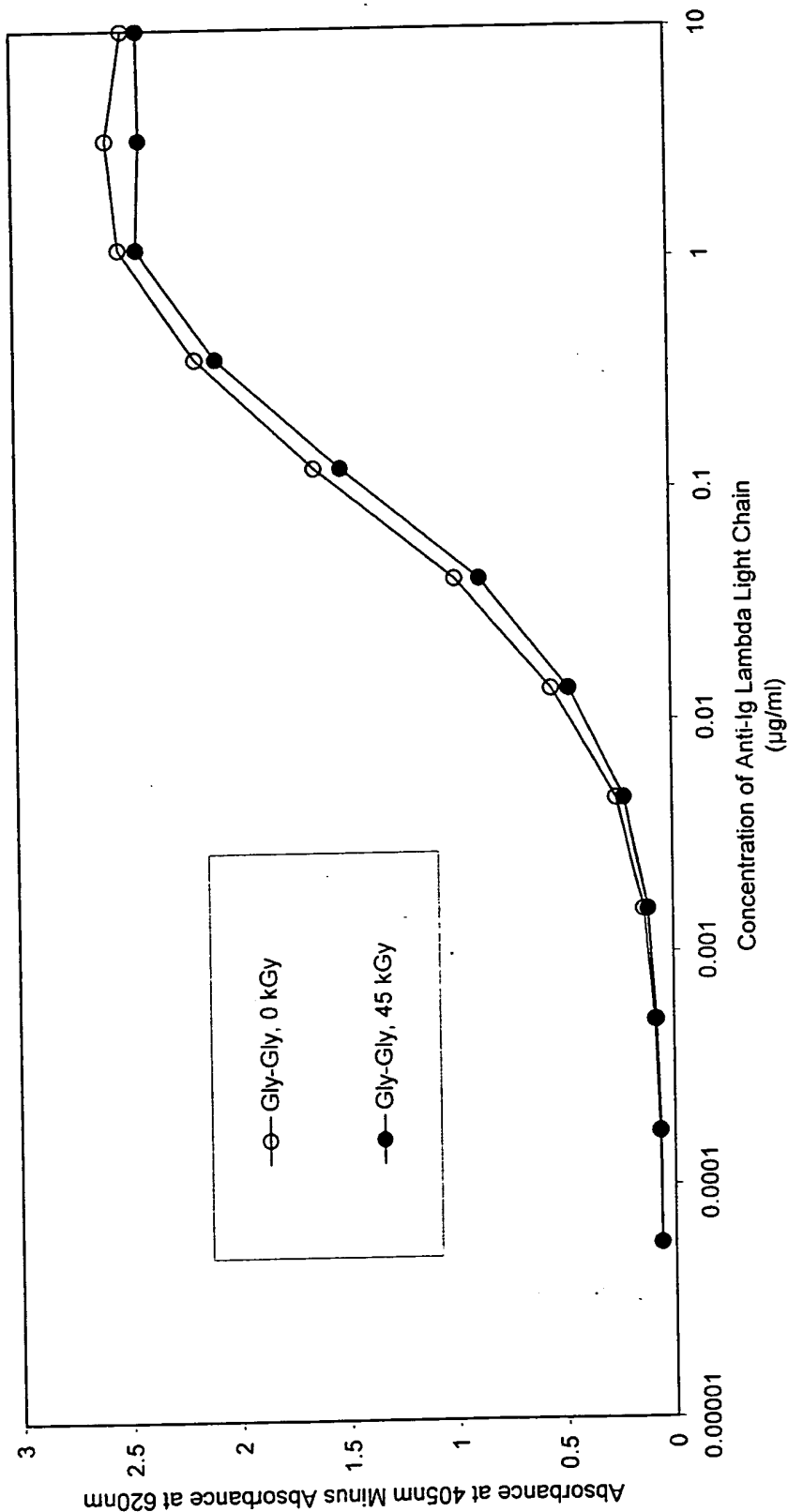


FIG. 18C

Gamma Irradiation of Freeze-Dried Anti-Insulin Monoclonal Antibody in the Presence or Absence of 20 mM Gly-Gly (and 1% BSA)

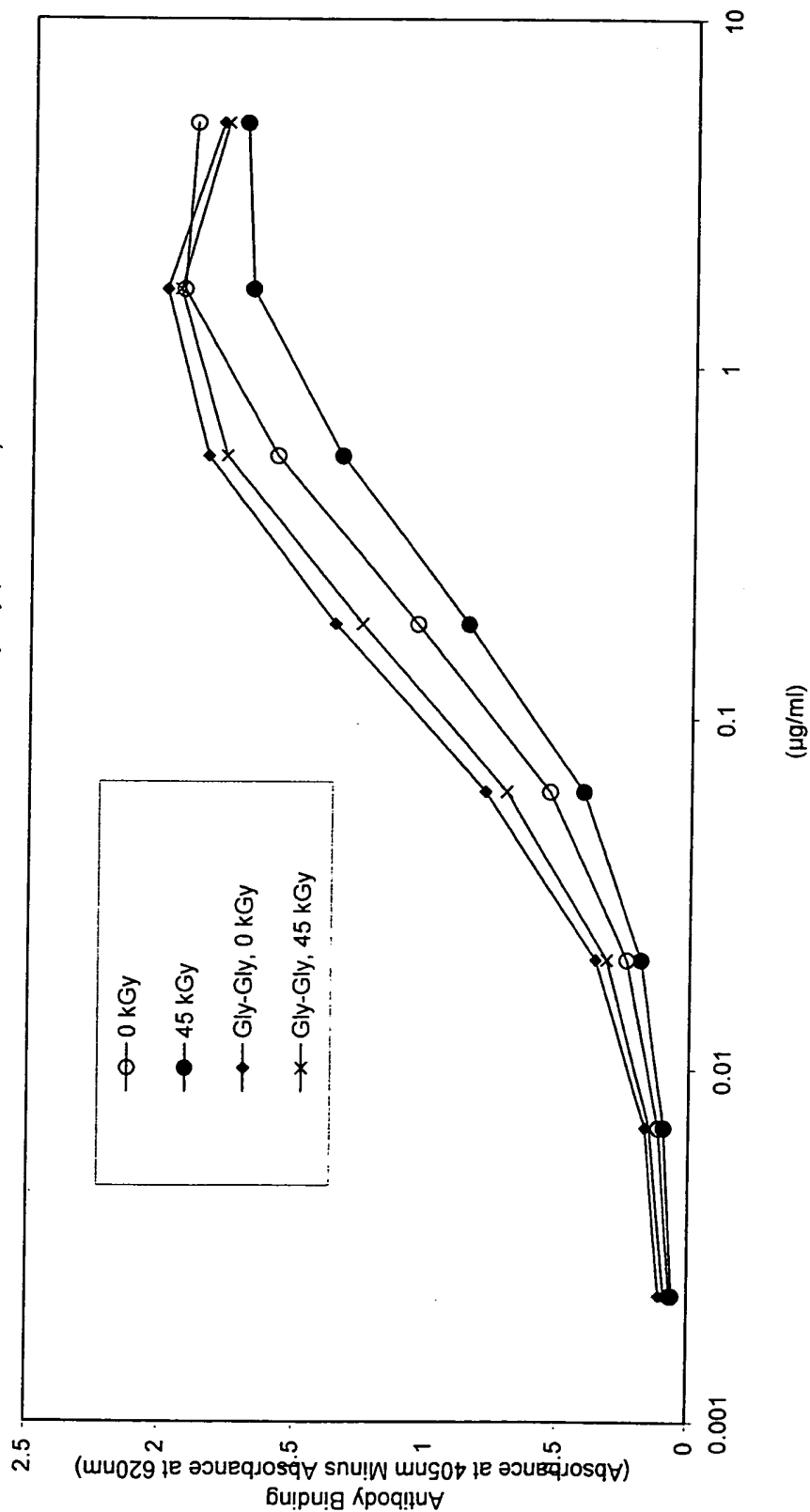


FIG. 19A

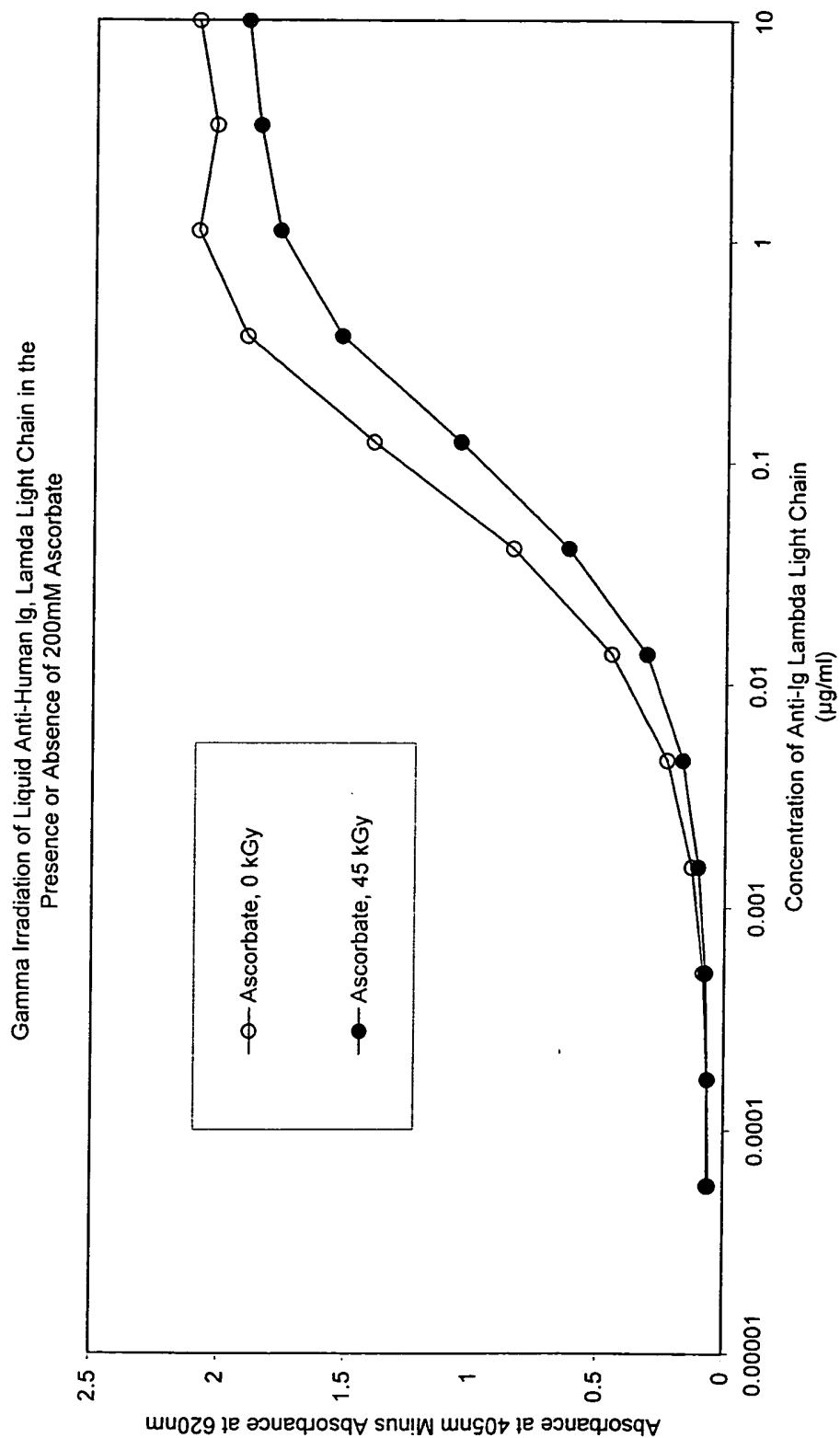


FIG. 2B

FIG. 19B



47/113

Gamma Irradiation of Liquid Anti-Human Ig, Lambda Light Chain in the Presence or Absence of 200mM Ascorbate and 200 mM Gly-Gly

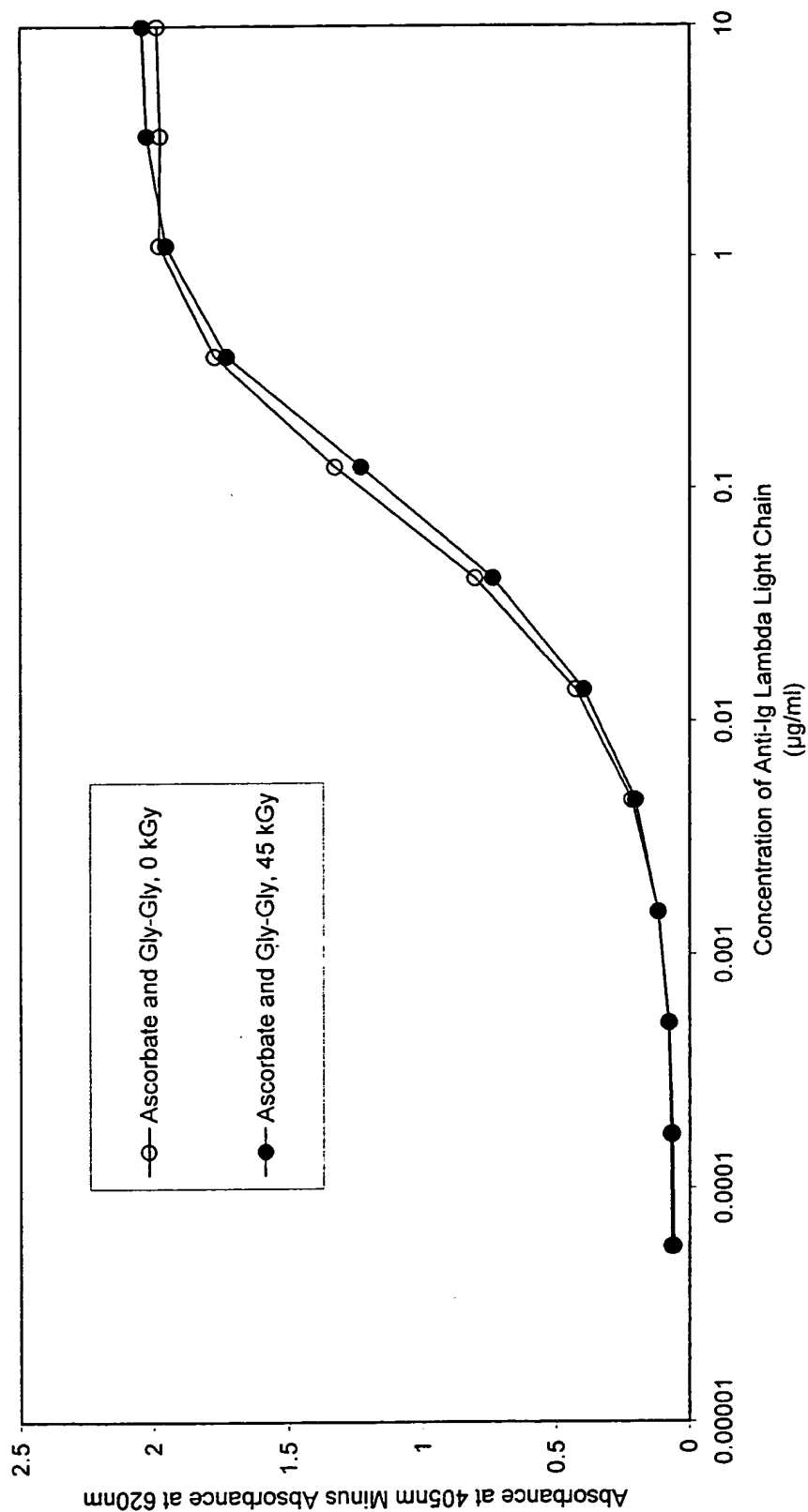


FIG. 19C

Gamma Irradiation of Liquid Anti-Human IgG1 in the  
Presence of 200 mM Ascorbate

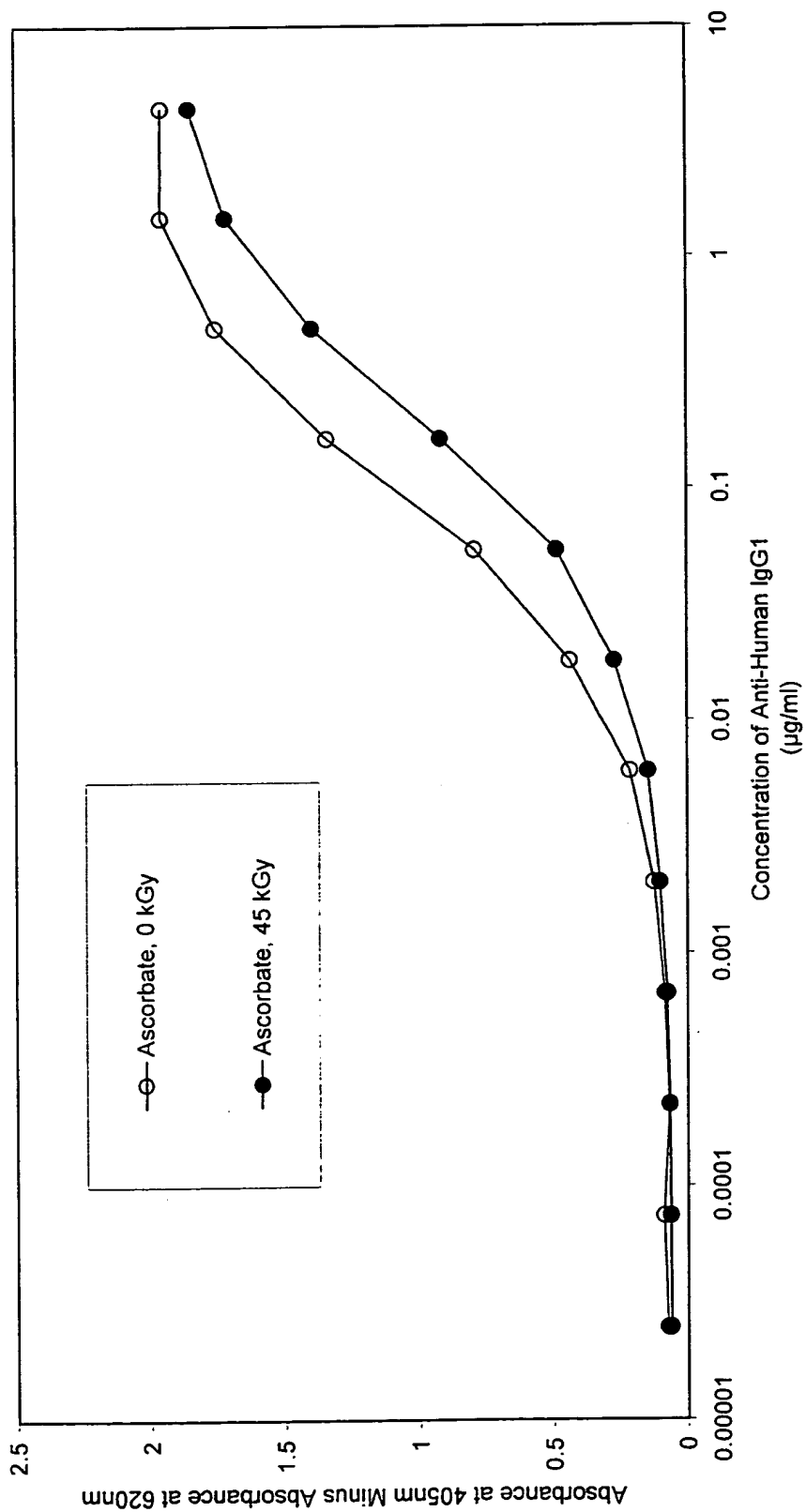


FIG. 19D





49/113

Gamma Irradiation of Freeze-Dried Anti-Insulin Monoclonal Antibody at a High Dose Rate (30 kGy/h) in the Presence or Absence of 20 mM Gly-Gly

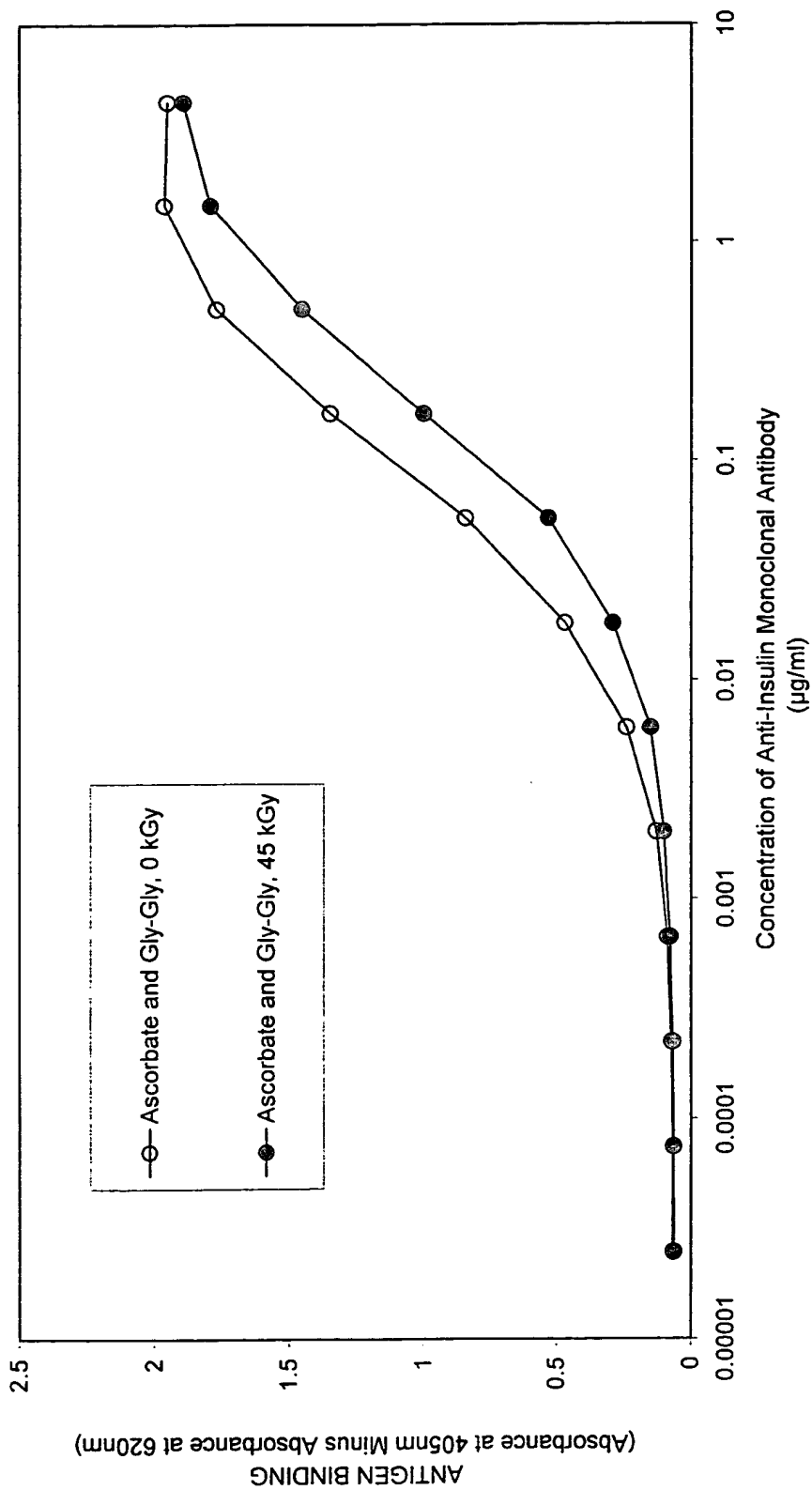


FIG. 19E

Gamma Irradiation of Liquid  
 IGIV in the Presence or Absence of 200 mM Ascorbate  
 Using Rubella IgG Assay

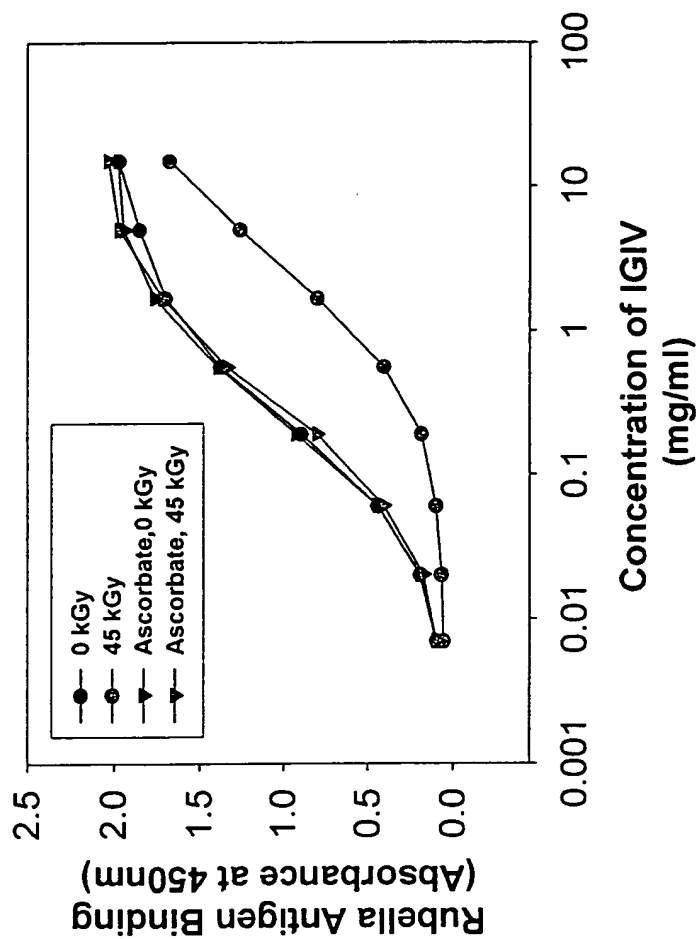


FIG. 20A

Gamma Irradiation of Liquid  
IGIV in the Presence or Absence of 200 mM Ascorbate and  
200 mM Gly-Gly Using Rubella IgG Assay

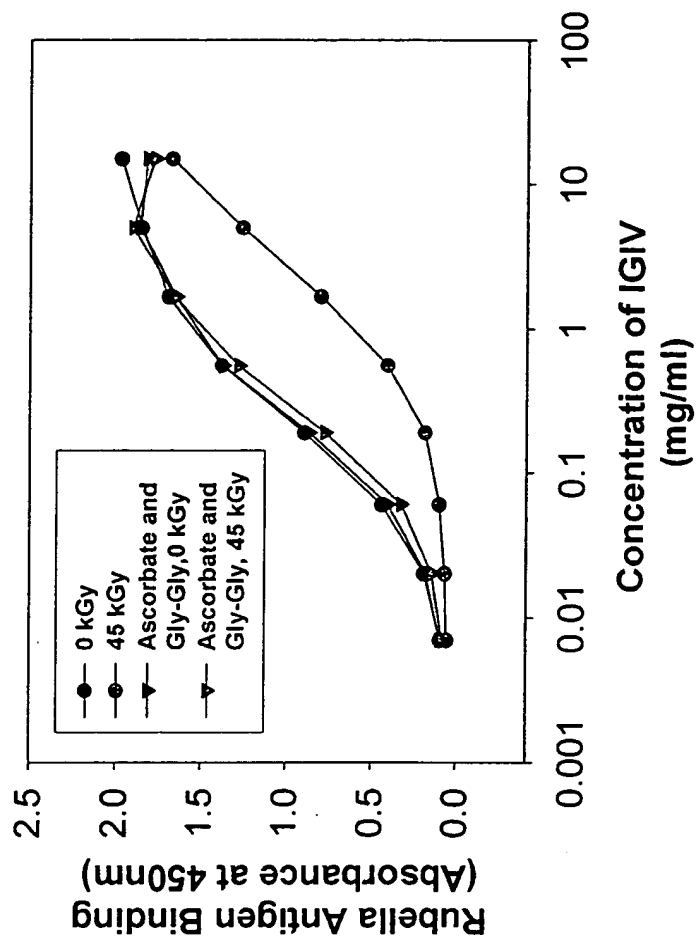


FIG. 20B

Gamma Irradiation of Liquid  
IGIV in the Presence or Absence of 200 mM Ascorbate and  
200 mM Gly-Gly Using Rubella IgG Assay

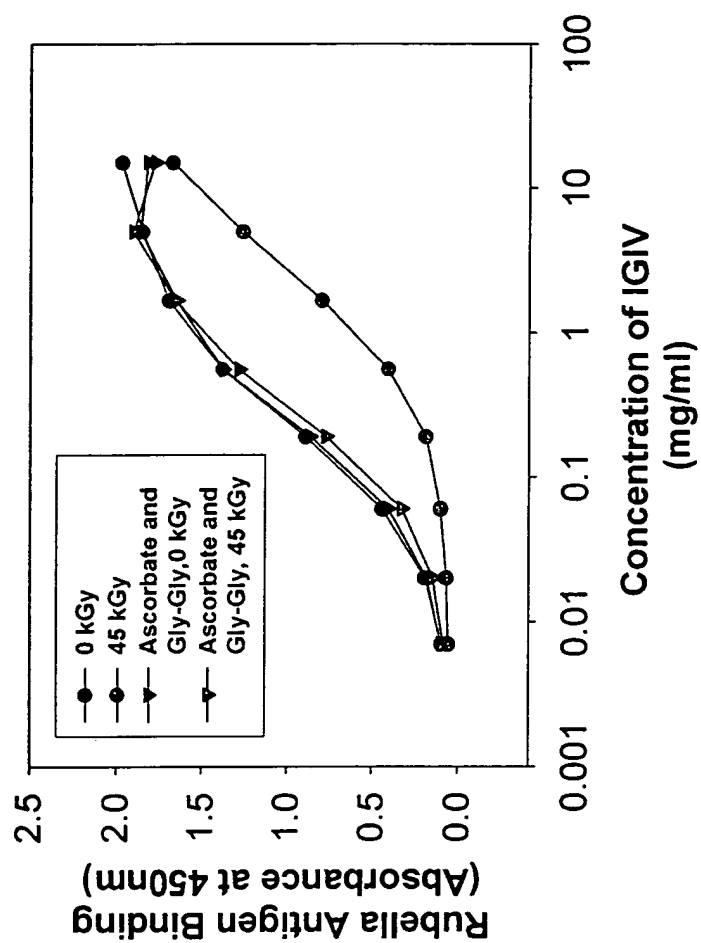


FIG. 20C

Gamma Irradiation of Liquid  
IGIV in the Presence or Absence of 200 mM Ascorbate  
Using Mumps Assay

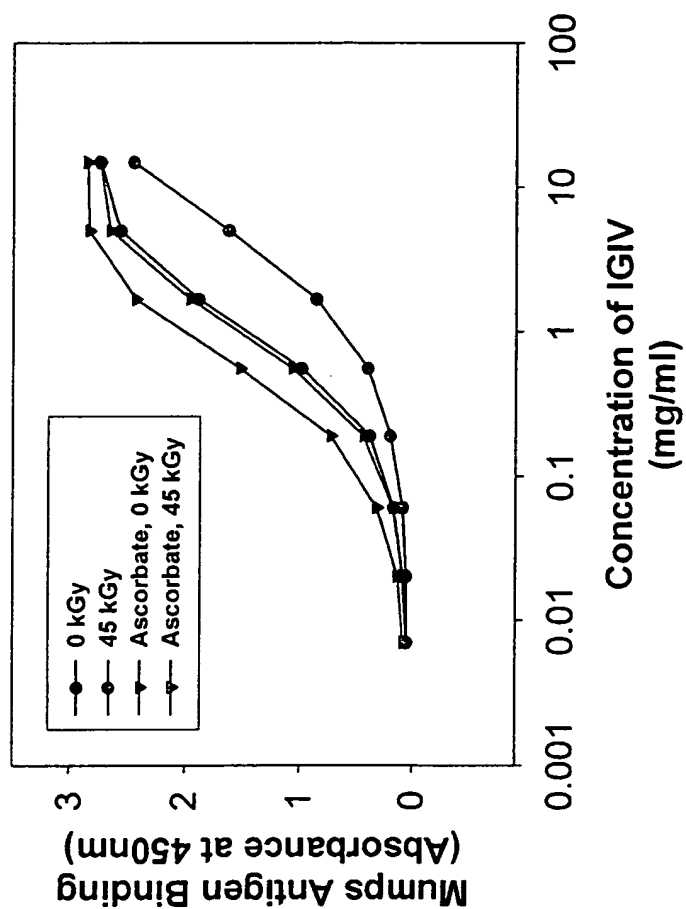


FIG. 20D

Gamma Irradiation of Liquid  
 IGIV in the Presence or Absence of 200 mM Ascorbate  
 and 200 mM Gly-Gly Using Mumps Assay

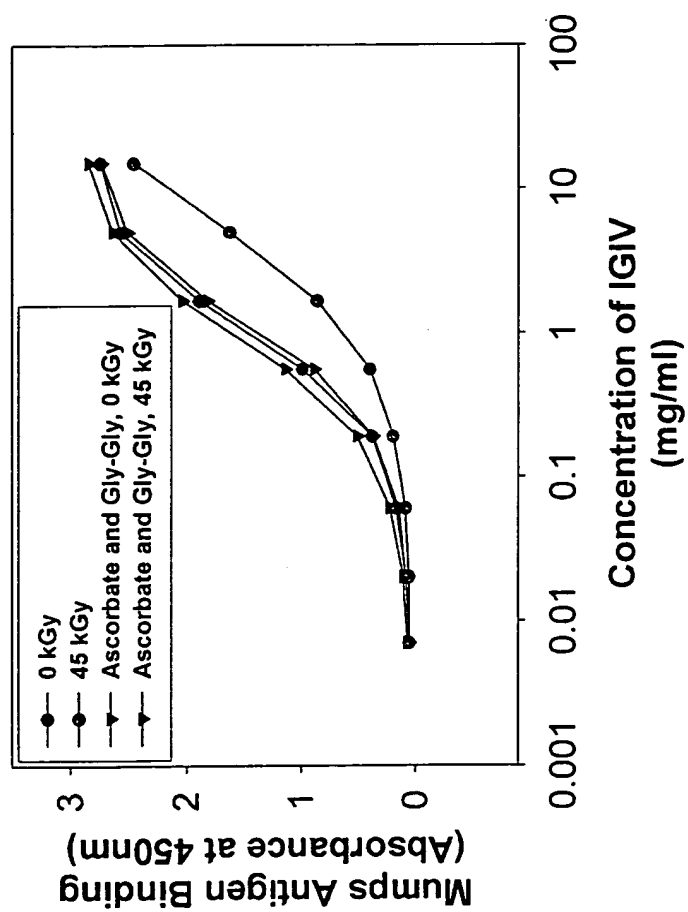


FIG. 20E

Gamma Irradiation of Liquid  
 IGIV in the Presence or Absence of 200 mM Ascorbate  
 Using CMV Assay

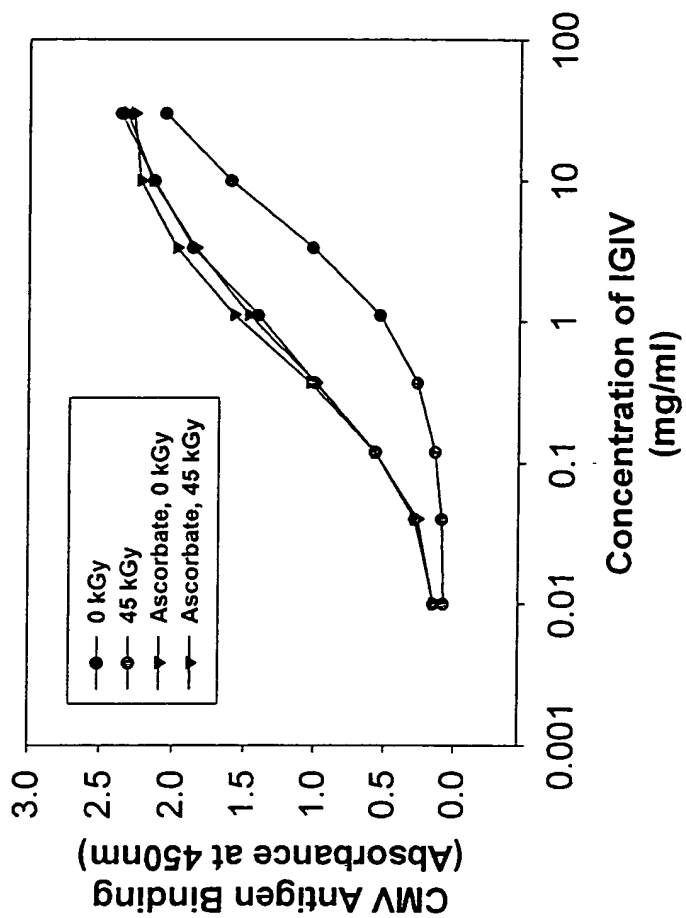


FIG. 20F

SDS-PAGE of Liquid IGIV

Liquid IGIV, Reduced 5-15%

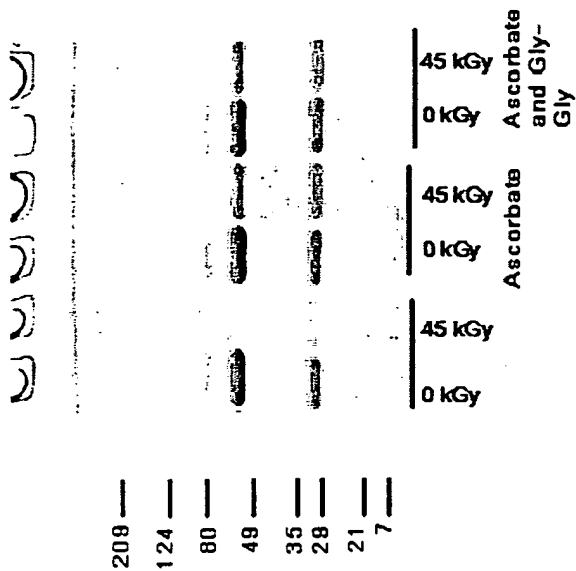


FIG. 20G



57/113

SDS-PAGE of Liquid IGIV

Liquid IGIV, Non-Reduced 5-15%

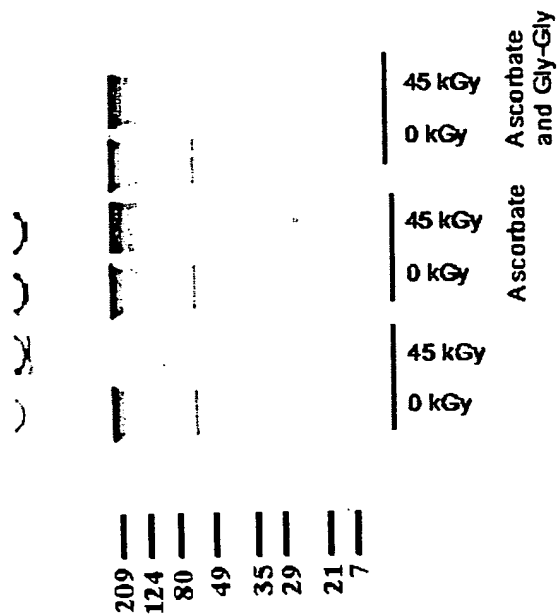


FIG. 20H

Gamma Irradiation of Freeze-Dried Anti-Insulin Monoclonal Antibody at a High Dose Rate (30 kGy/h) in the Presence or Absence of 20 mM Ascorbate

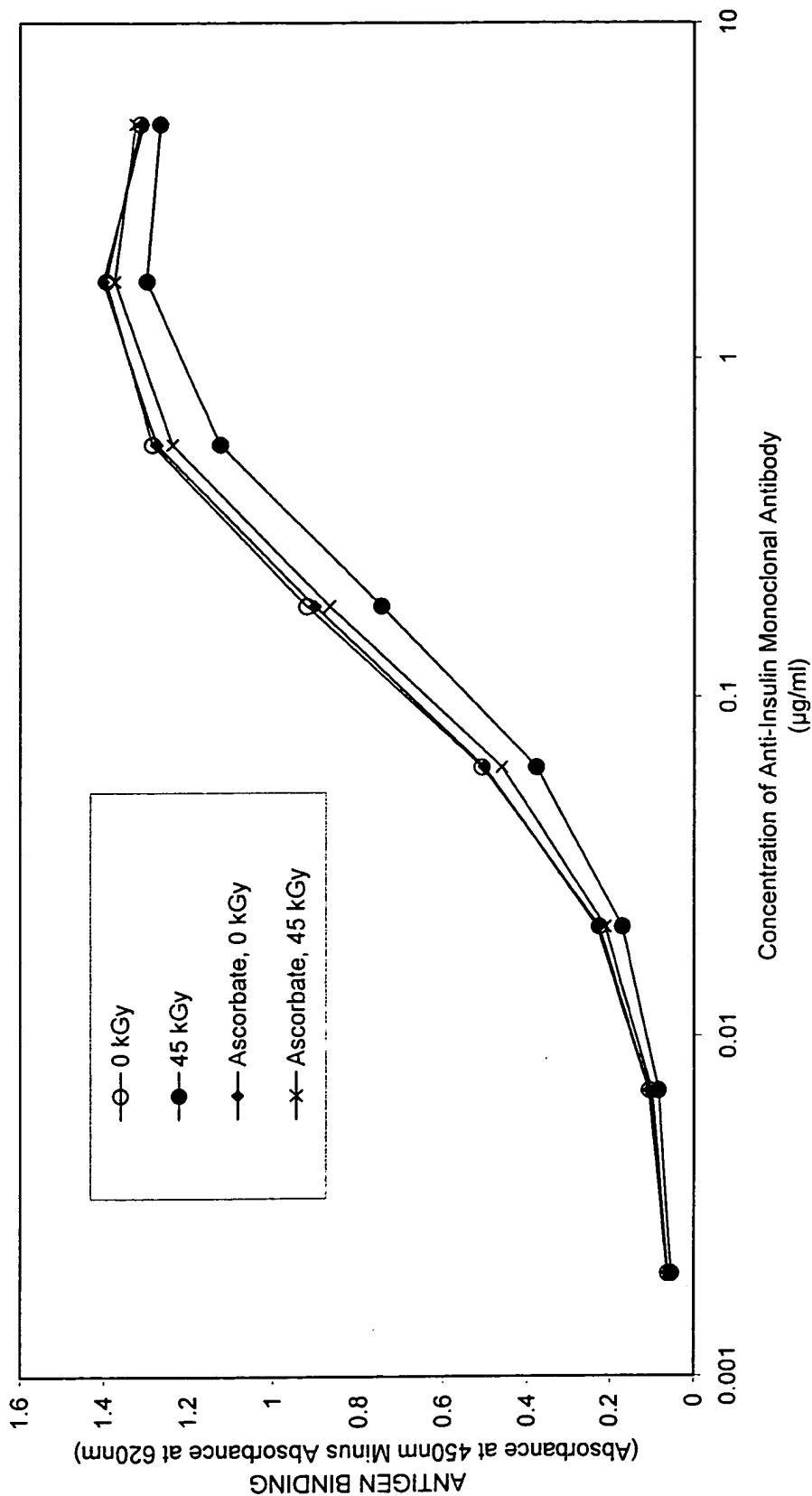


FIG. 21A



59/113

Gamma Irradiation of Freeze Dried Anti-Insulin Monoclonal Antibody at a High Dose Rate (30 kGy/h) in the Presence of 20 mM Gly-Gly

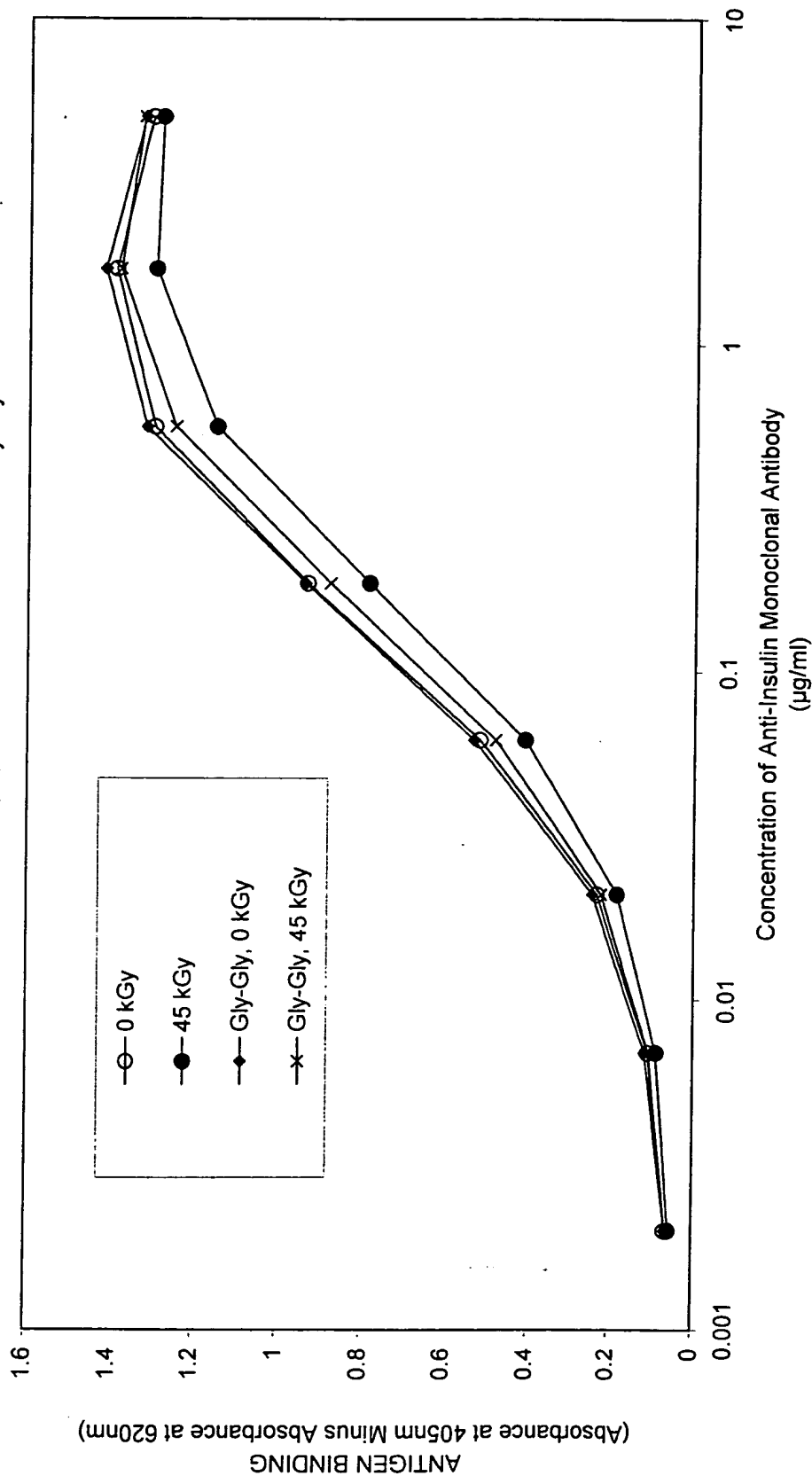


FIG. 21B

60/113

Gamma Irradiation of Freeze-Dried Anti-Insulin Monoclonal Antibody at a  
 High Dose Rate (30 kGy/h) in the Presence or Absence of 20mM Ascorbate and 20 mM Gly-Gly

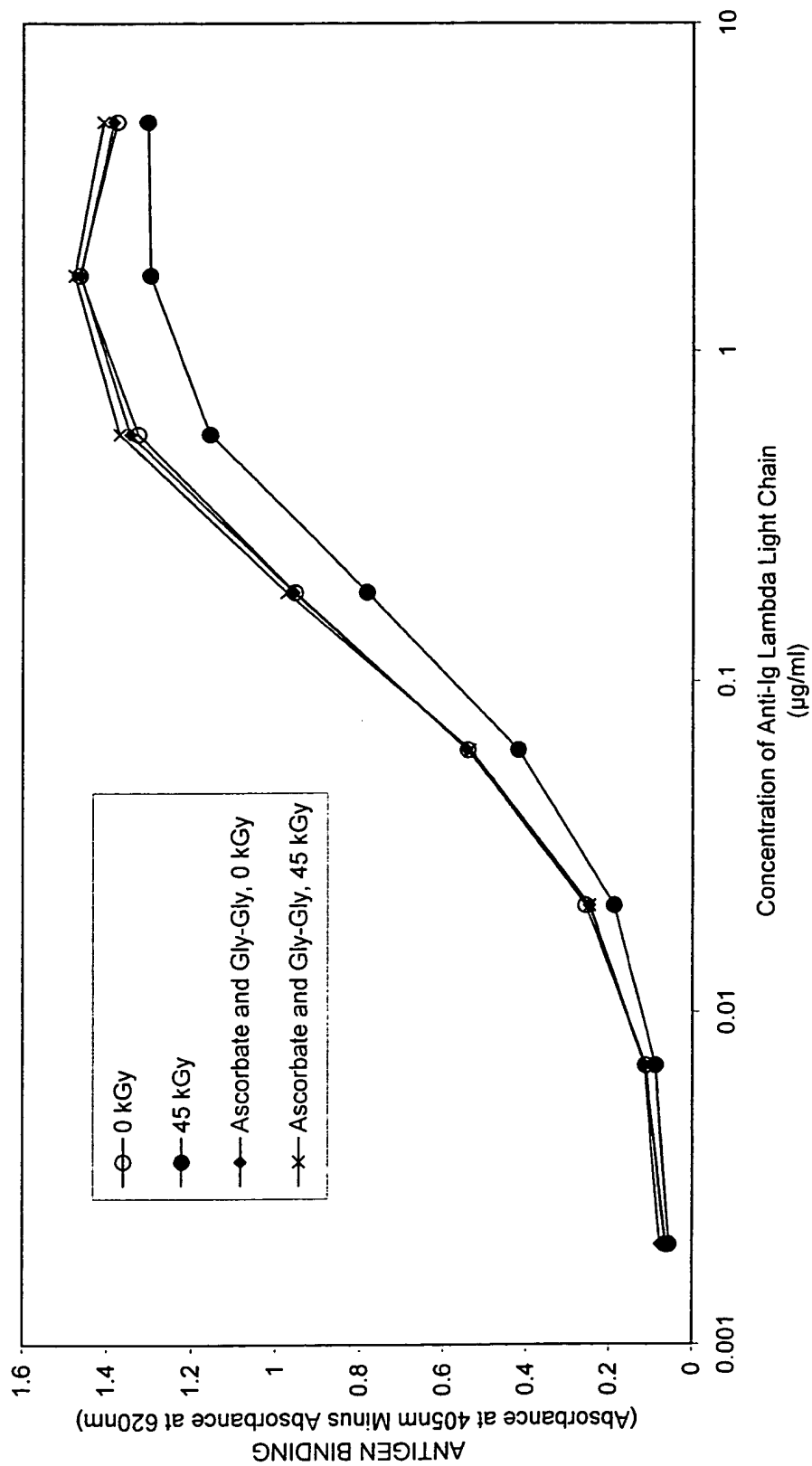


FIG. 21C

Gamma Irradiation of Anti-Insulin Monoclonal Antibody in the Presence or Absence of 200mM Ascorbate

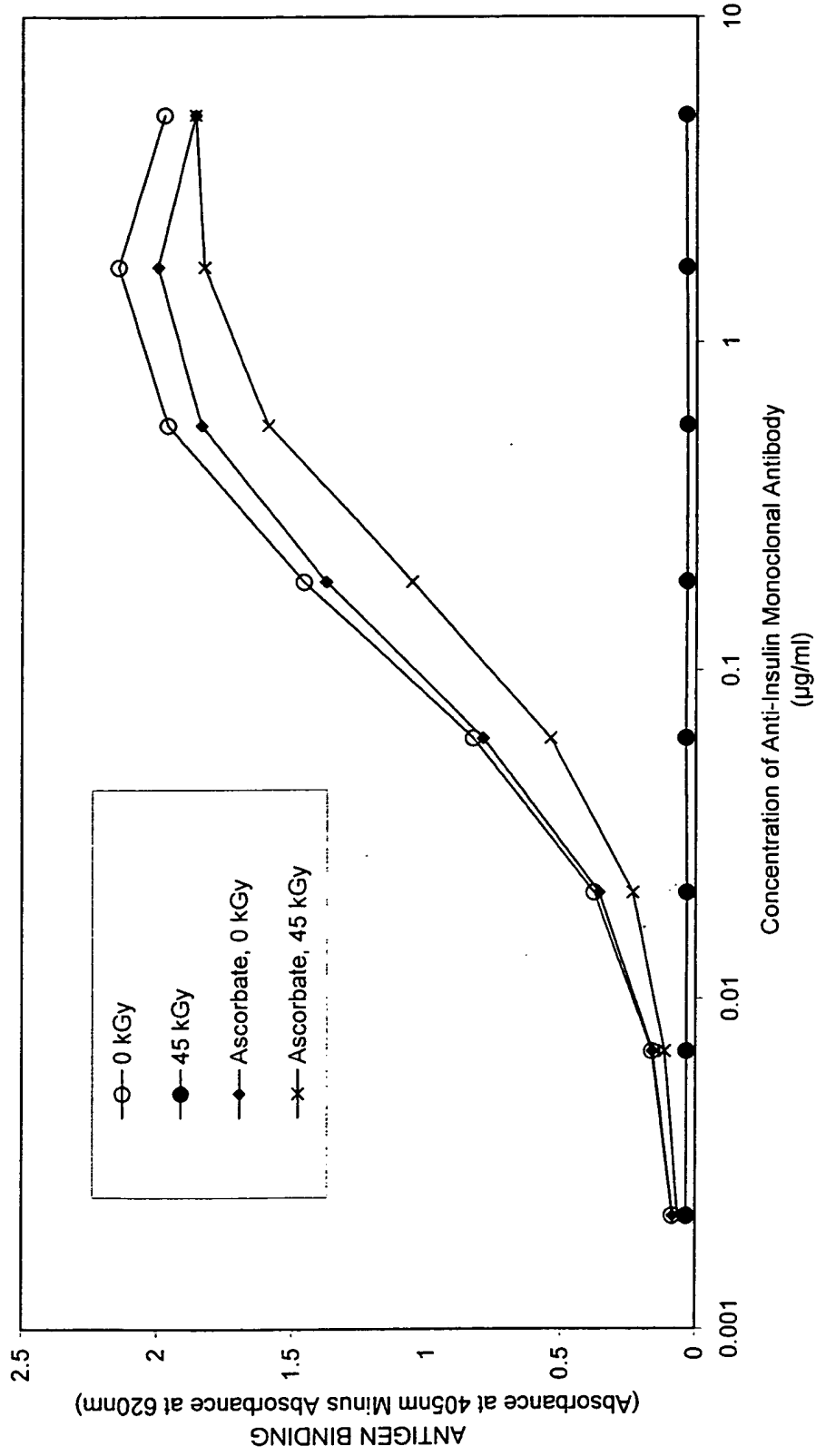


FIG. 22A

62/113

Gamma Irradiation of Anti-Insulin Monoclonal Antibody in the Presence or Absence of 200mM Ascorbate and 200mM Gly-Gly

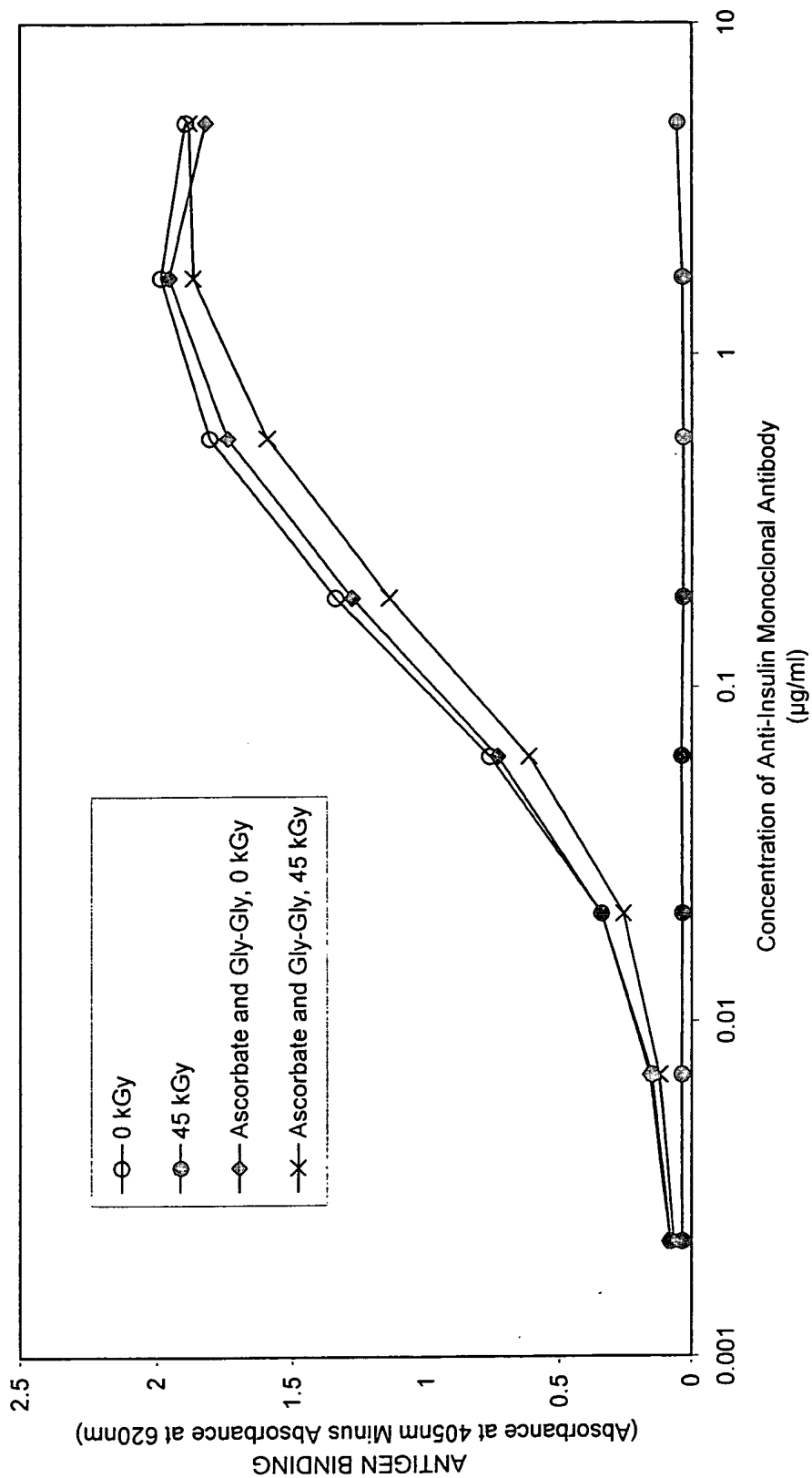


FIG. 22B

63/113

# SDS-PAGE for a Glycosidase

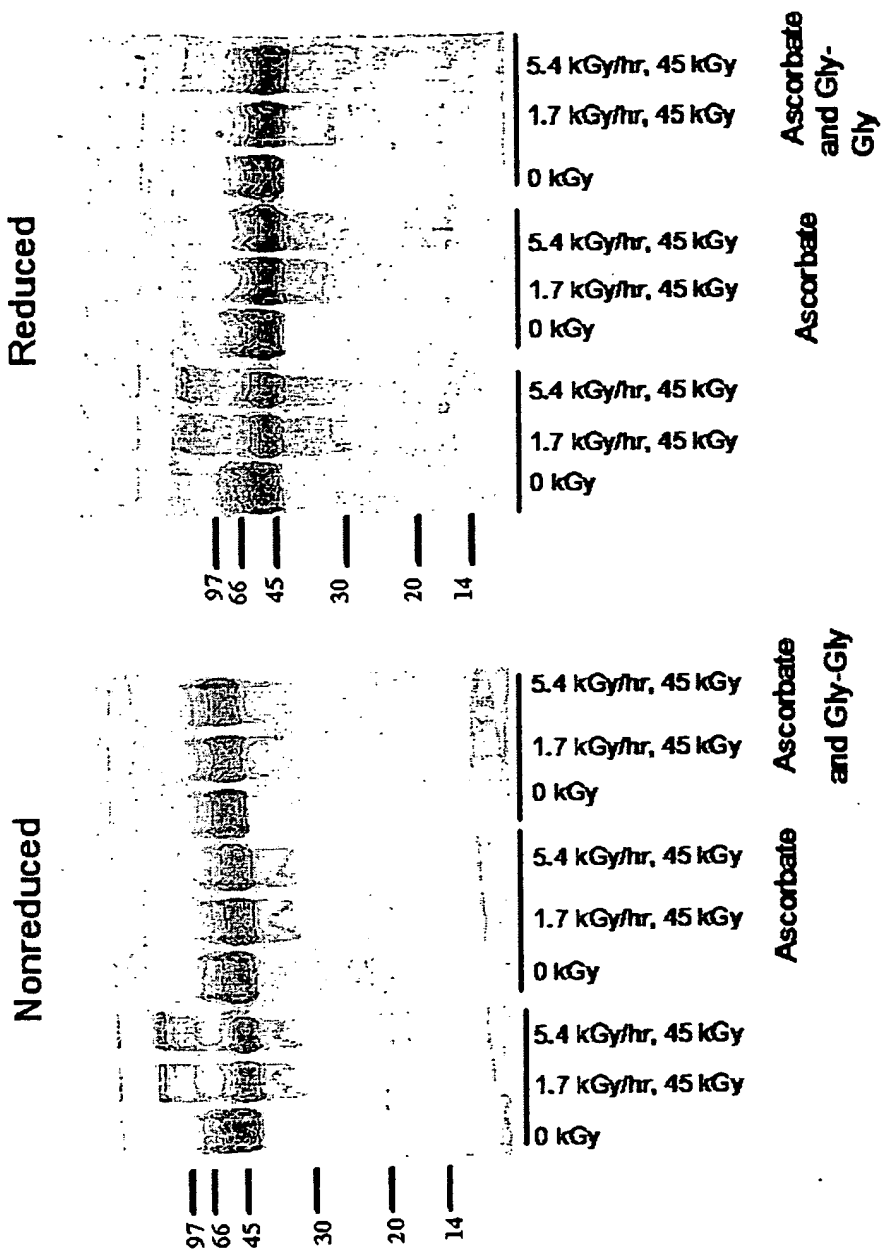


FIG. 23A

# SDS-PAGE for a Sulfatase Reduced

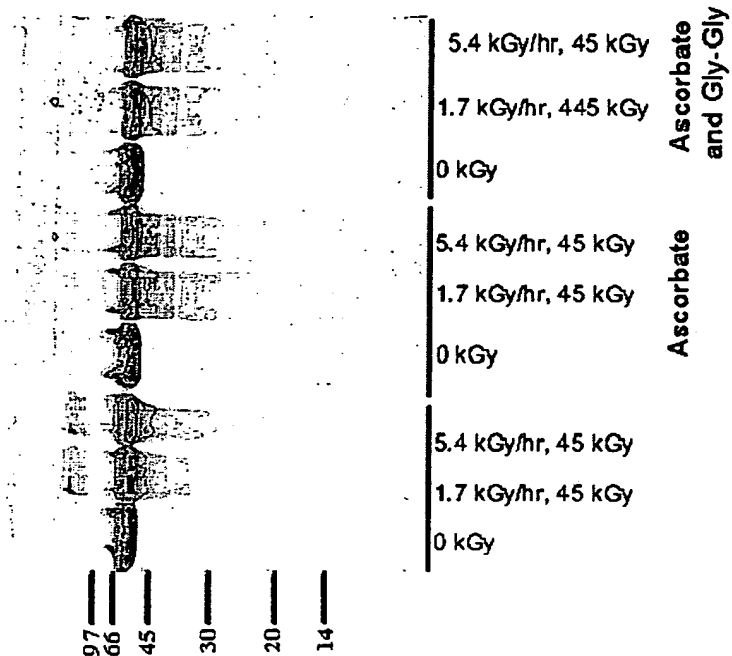


FIG. 23B



Gamma Irradiation of a Glycosidase In the Presence or Absence  
of Ascorbate Alone or in Combination with Gly-Gly

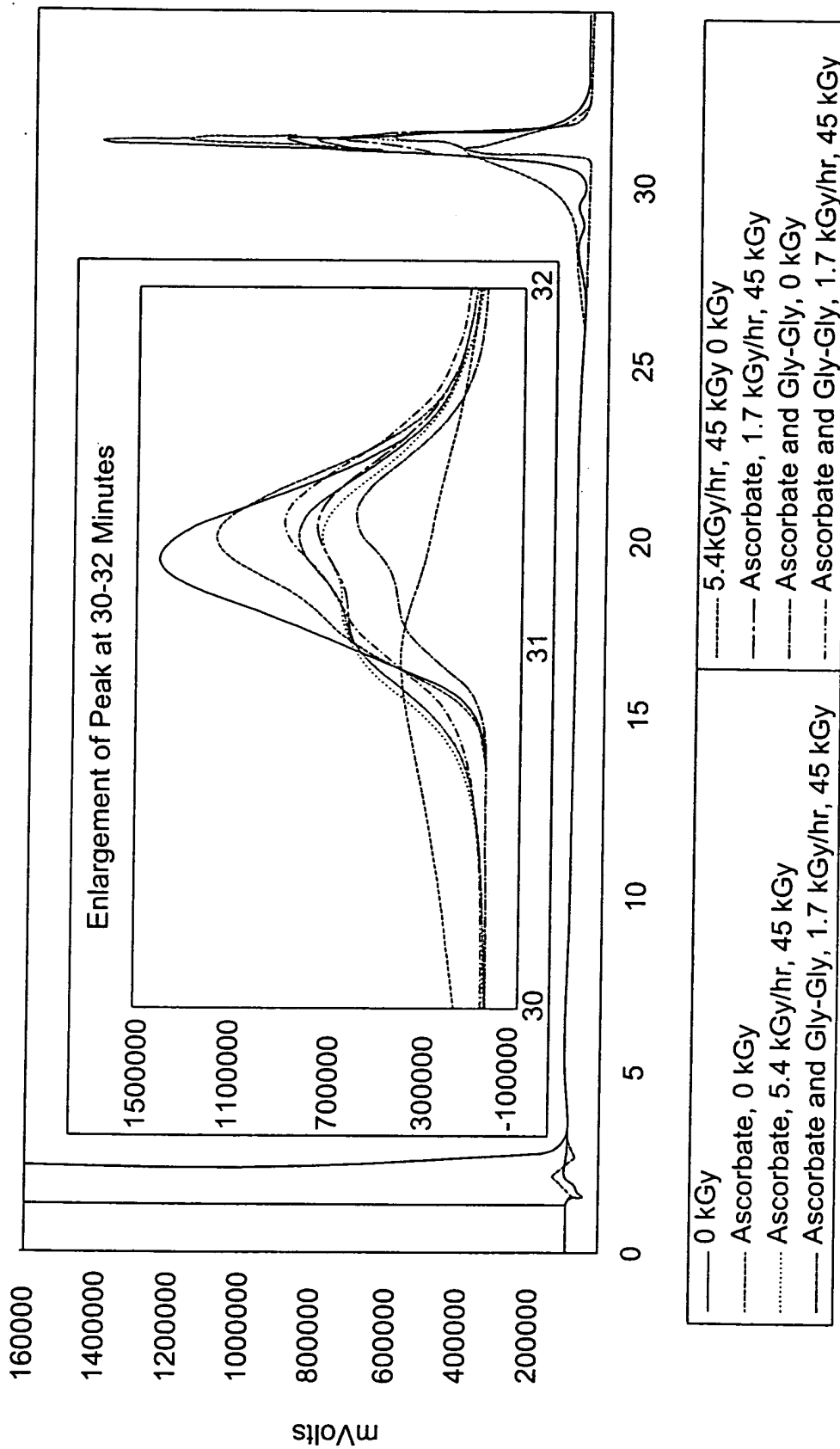


FIG. 24



66/113

Gamma Irradiation of Liquid Anti-Insulin Monoclonal Antibody in the Presence or Absence of 200mM Ascorbate Alone or in Combination with 200mM Gly-Gly

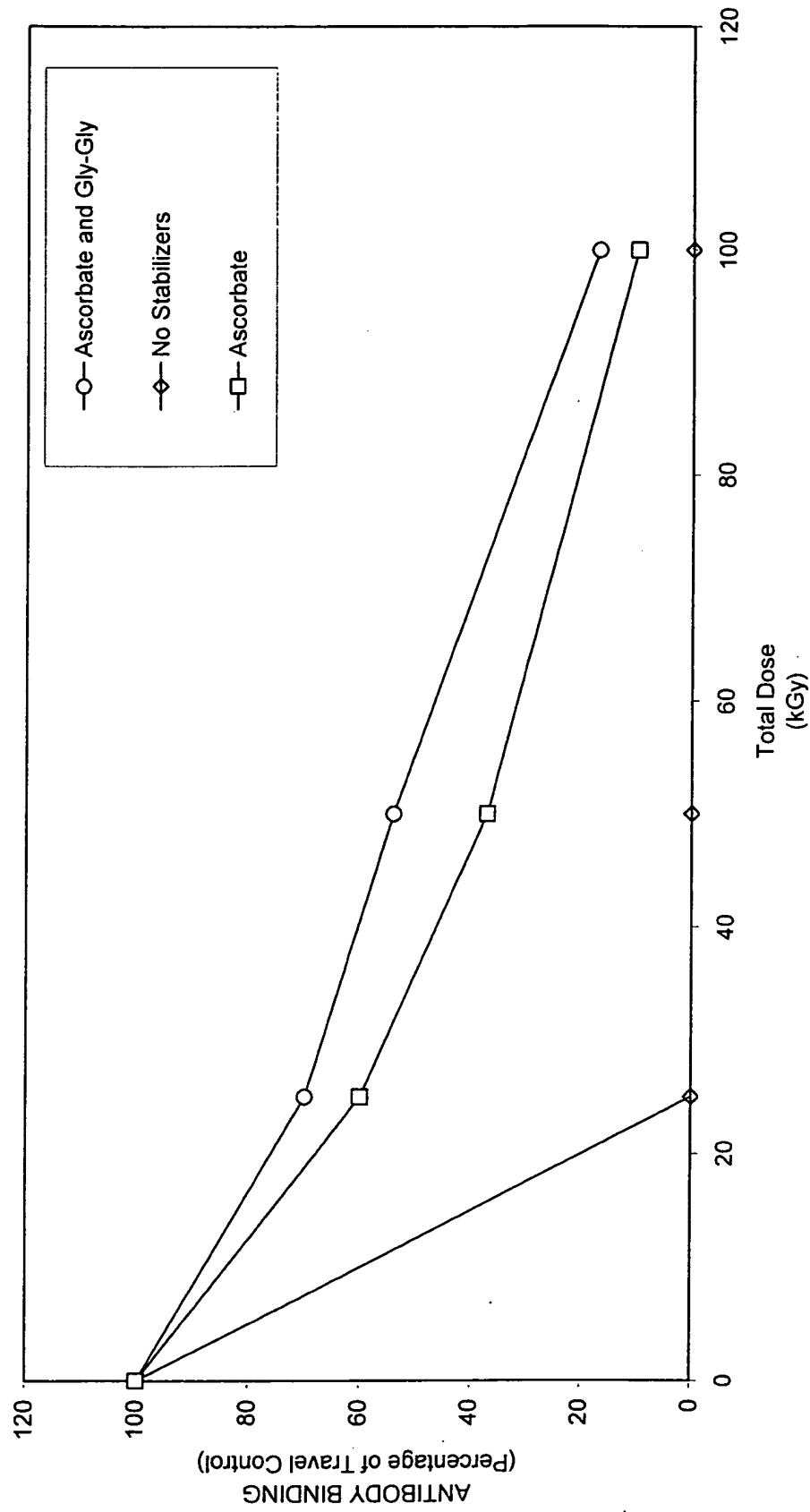


FIG. 25

67/113

Gamma Irradiation of Liquid Urokinase, with L-Carnosine, at 45 kGy in the Presence or Absence of 50mM Ascorbate

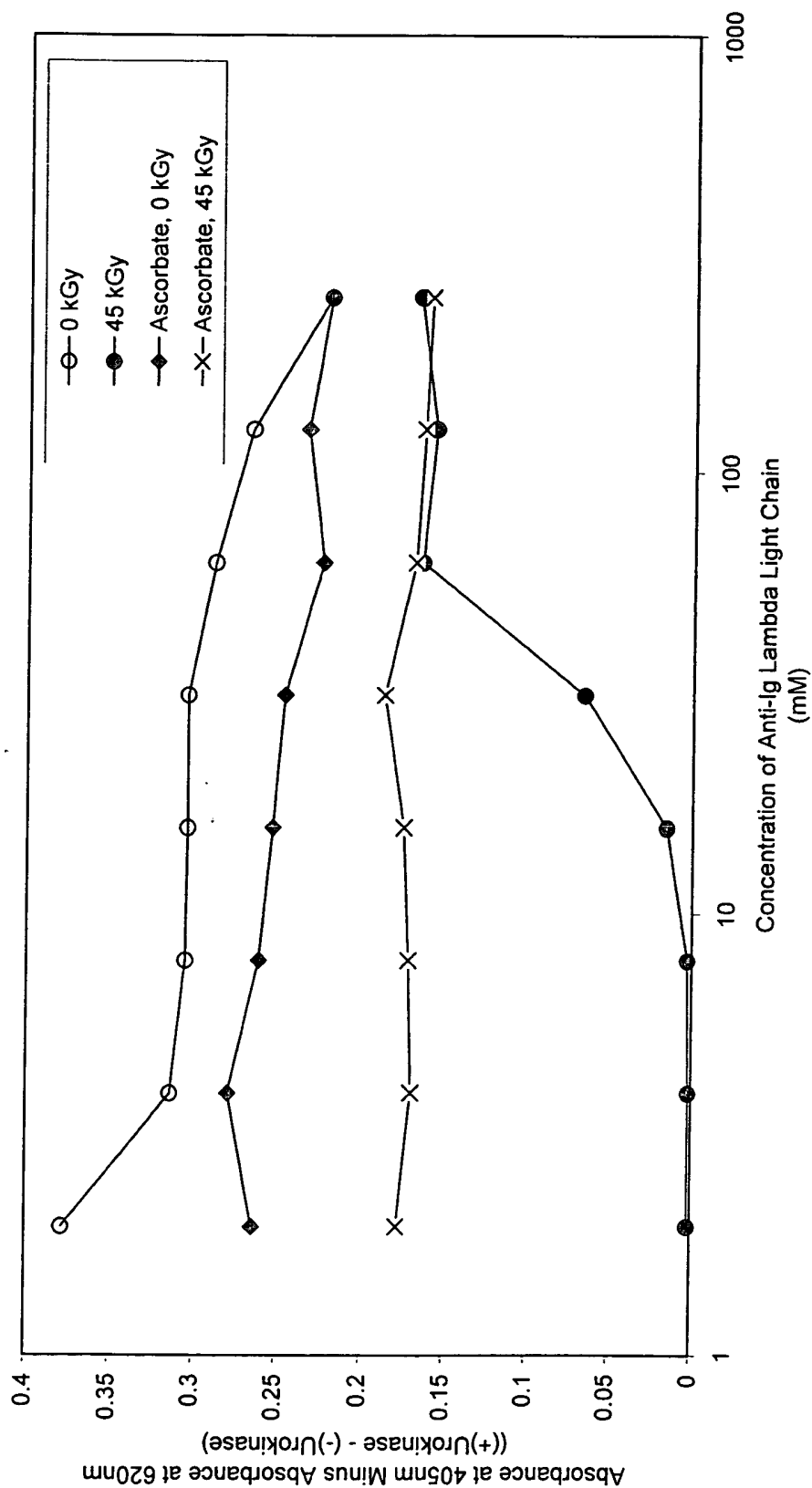


FIG. 26

050201.iv.027a Gamma Irradiation of Liquid Anti-Human Ig, Lambda Light Chain in the Presence or Absence of 200mM Ascorbate

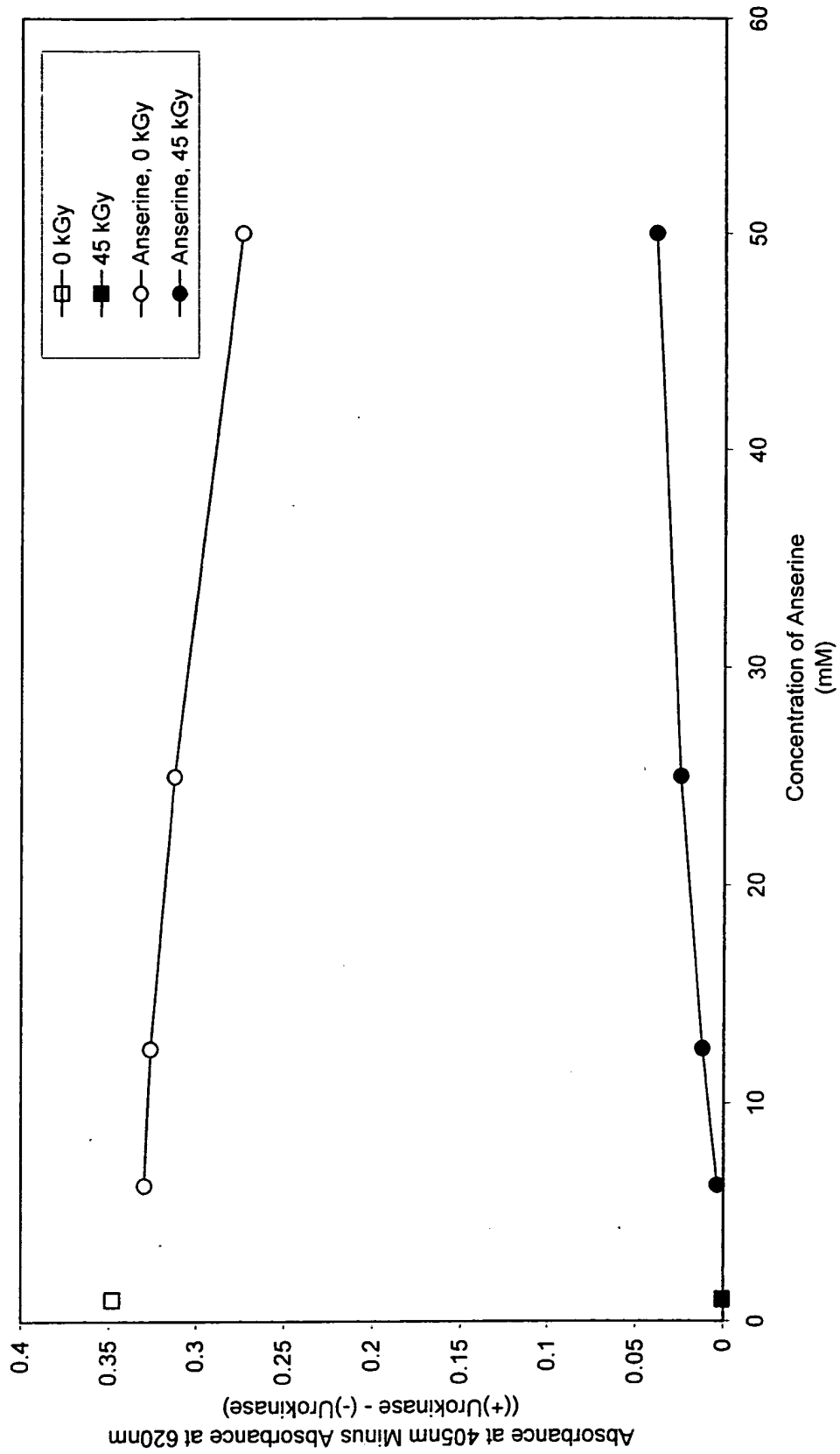


FIG. 27

050201.iv.027a Gamma Irradiation of Liquid Anti-Human Ig, Lambda Light Chain in the Presence or Absence of 200mM Ascorbate

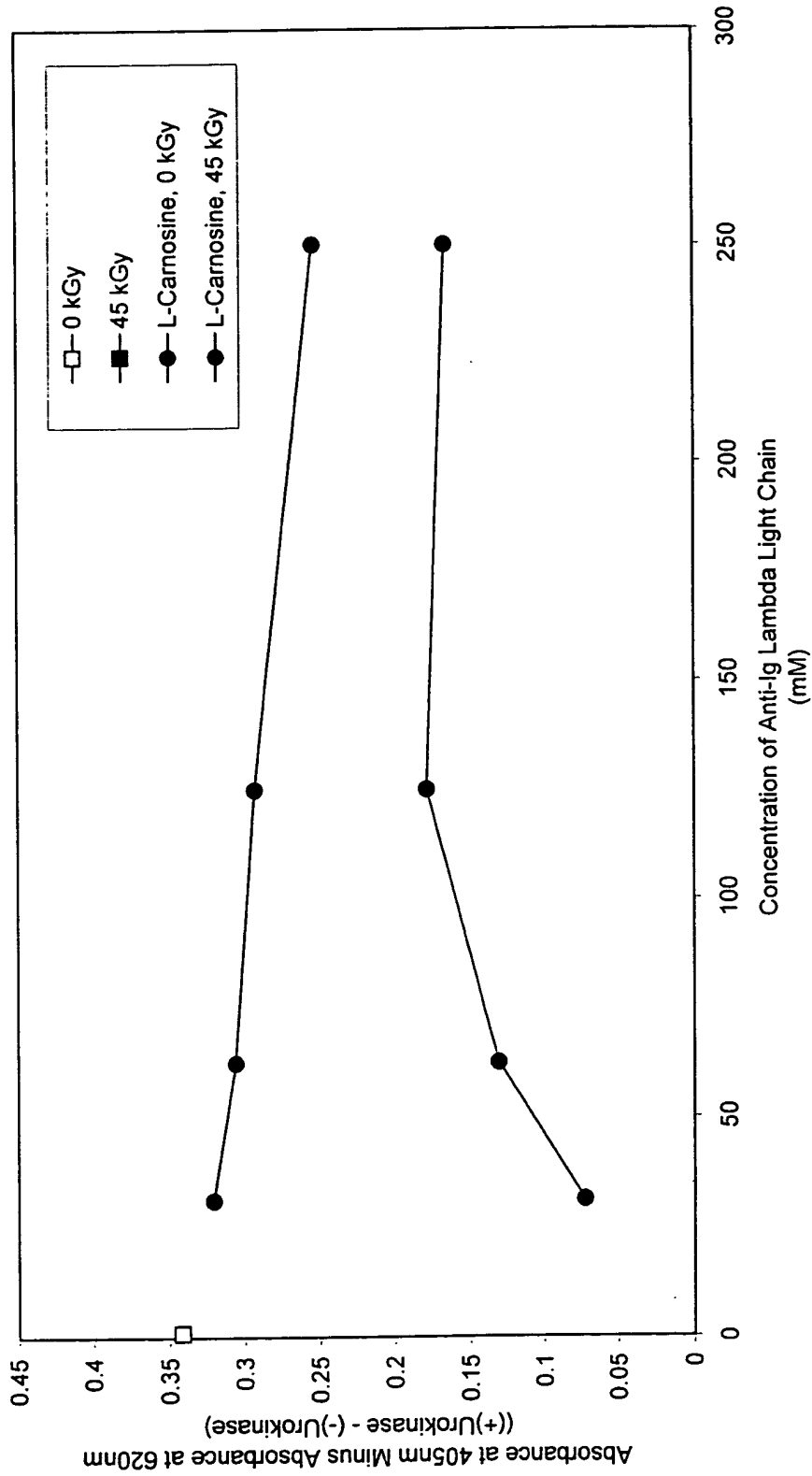


FIG. 28



70/113

050201.iv.027a Gamma Irradiation of Liquid Anti-Human Ig, Lambda Light Chain in the Presence or Absence of 200mM Ascorbate

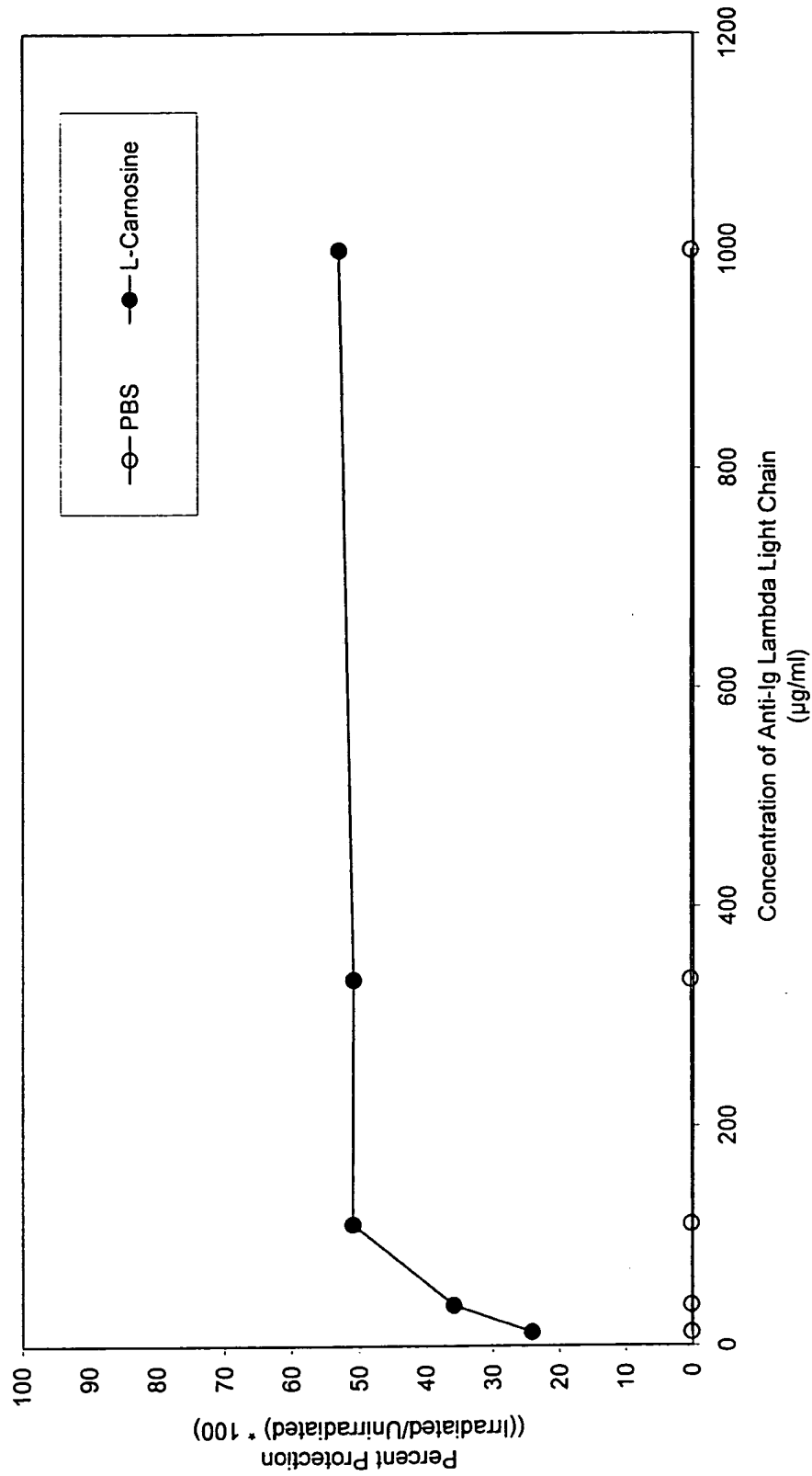


FIG. 29

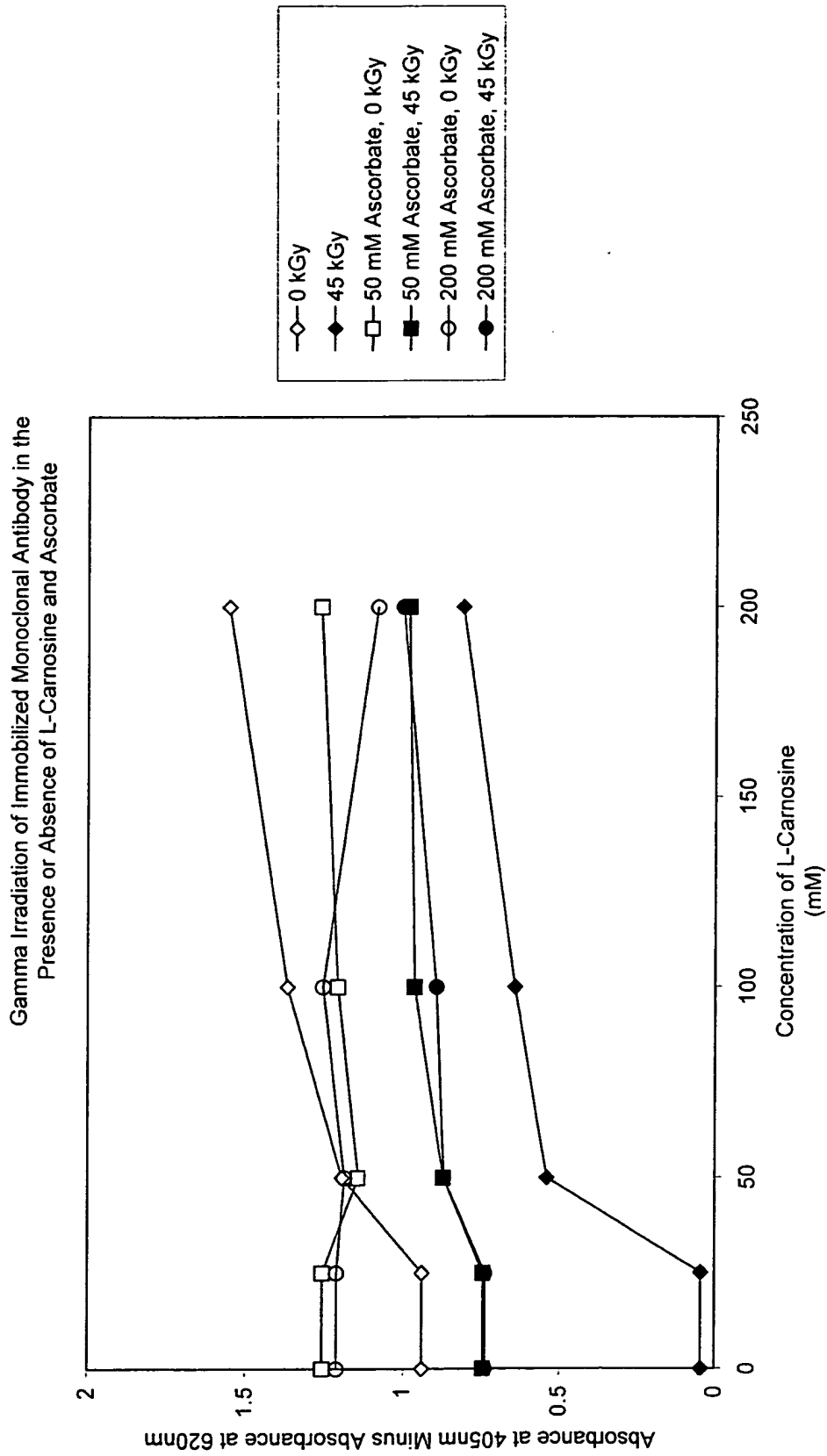


FIG. 30

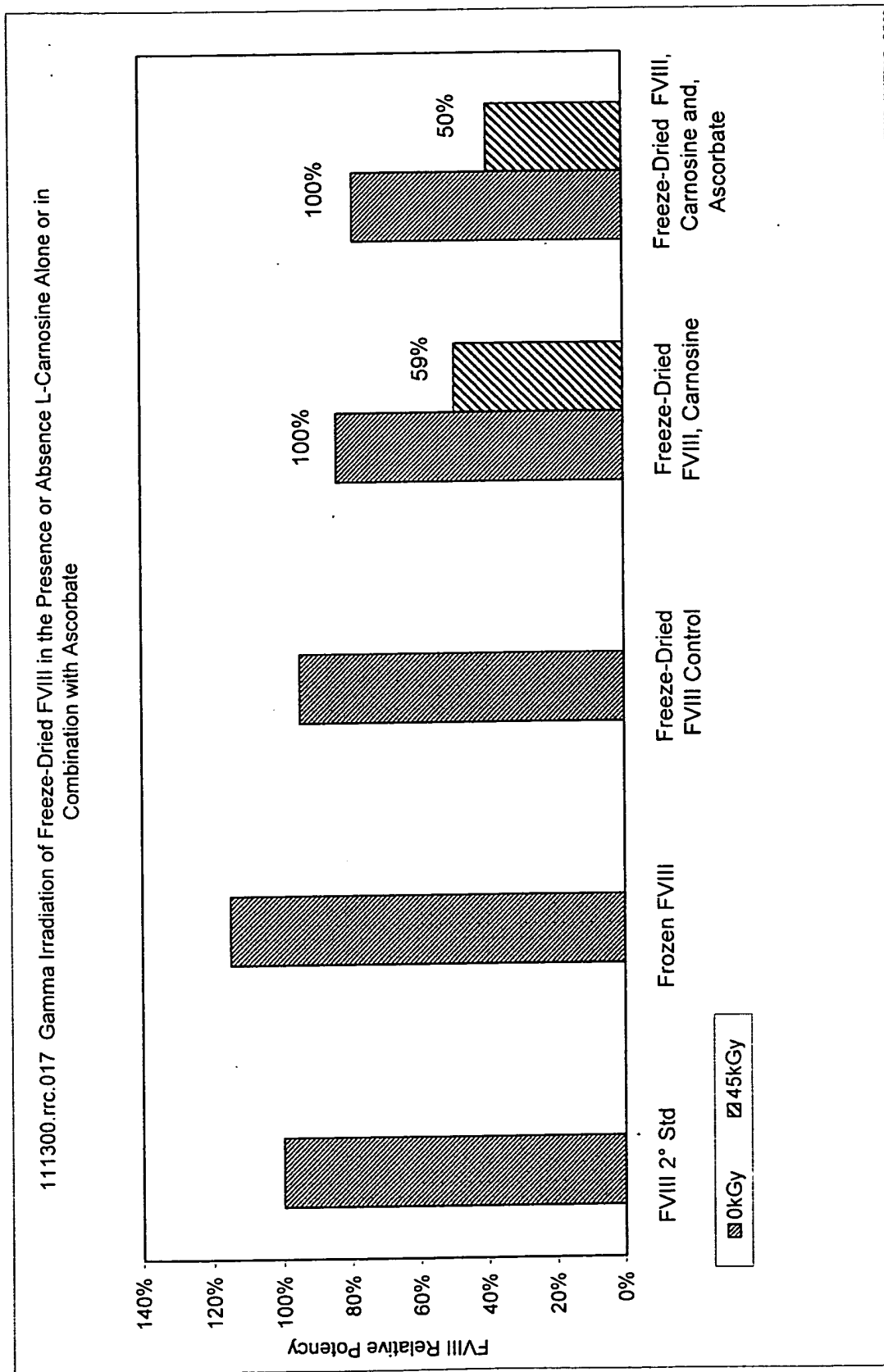


FIG. 31



# Gamma Irradiation of Dried and Powder PPF

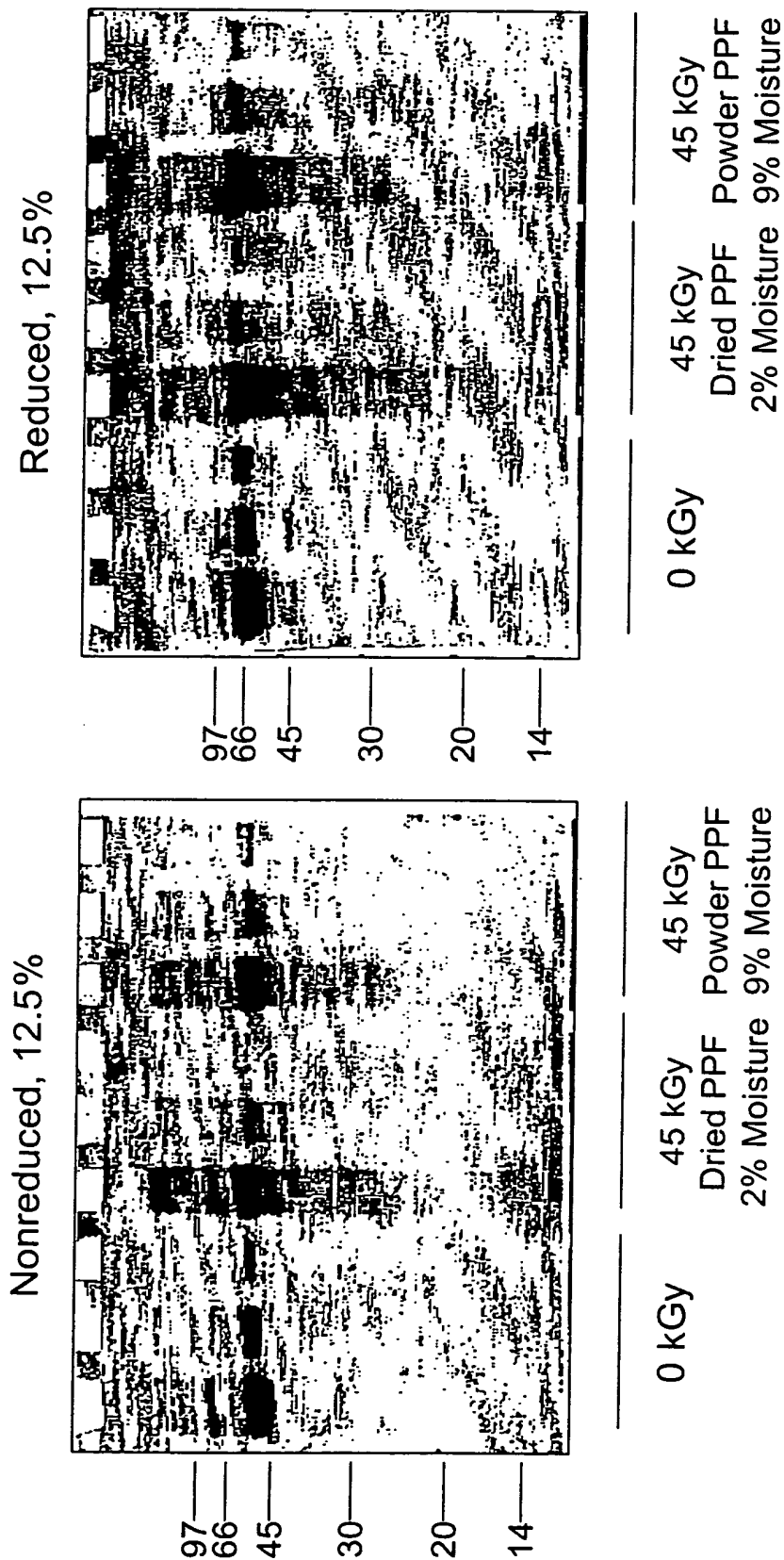


FIG. 32A



74/113

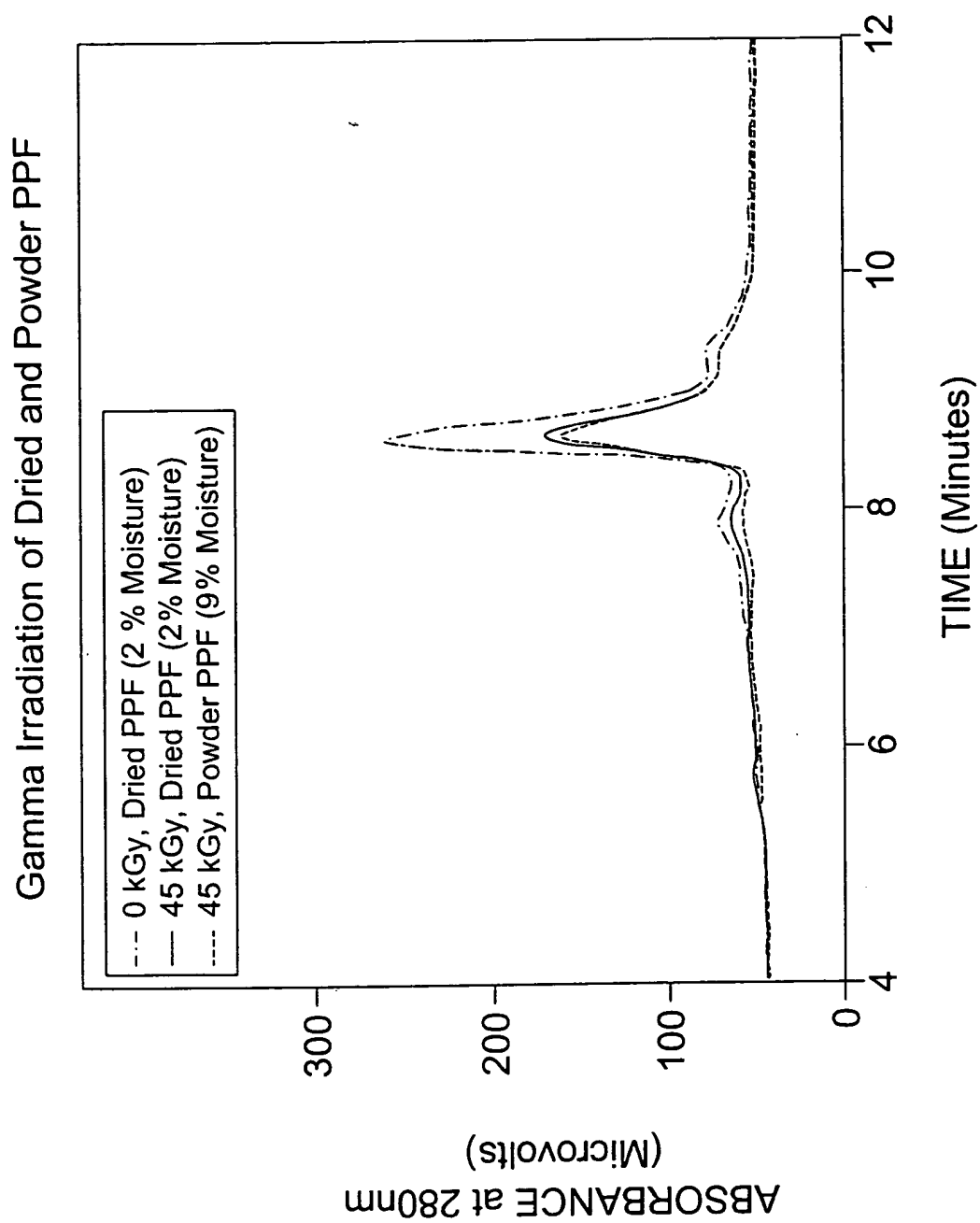


FIG. 32B



75/113

# Gamma Irradiation of Dried and Powder PPF

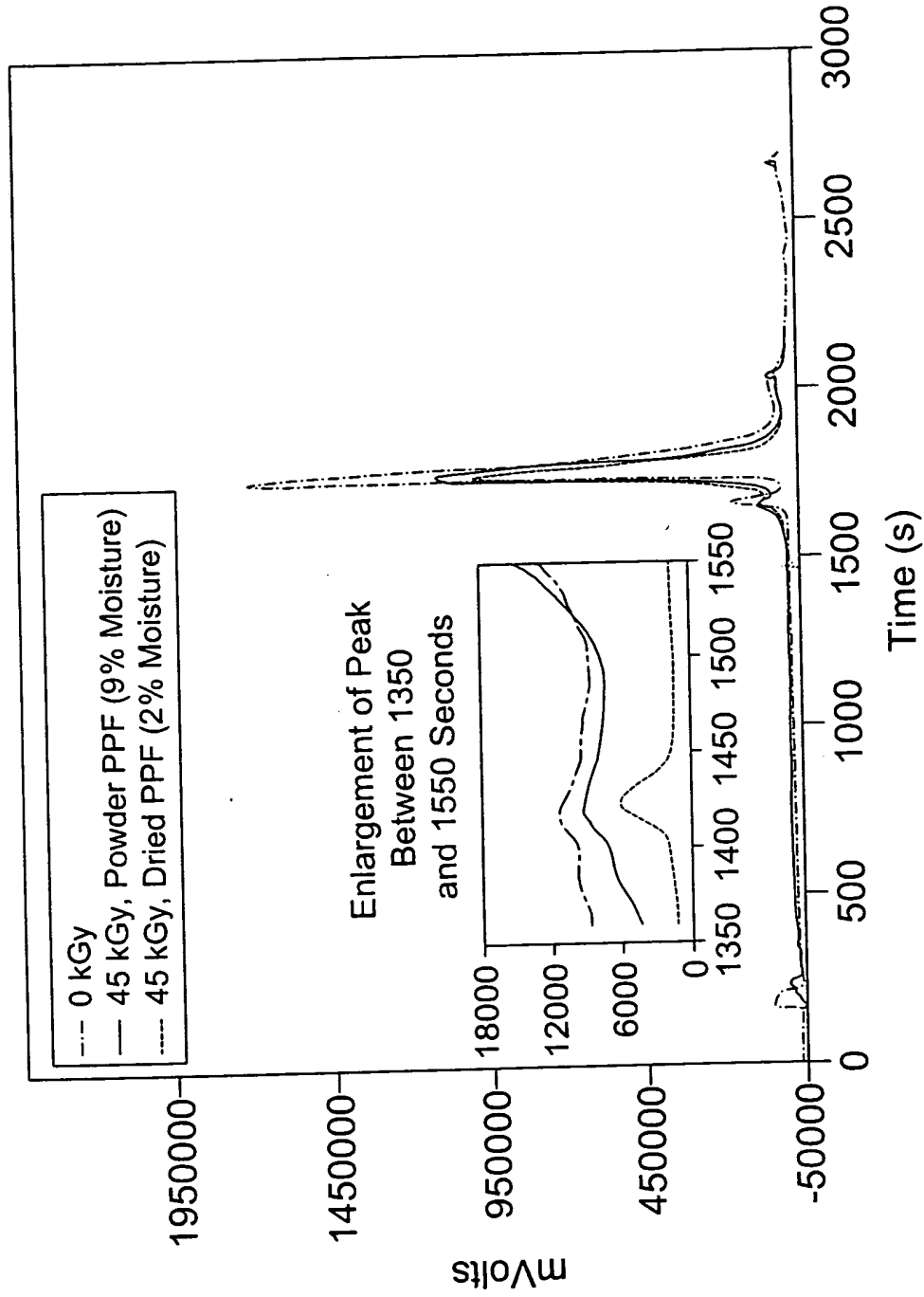


FIG. 32C

Gamma Irradiation (to 25 and 50 kGy)  
of 25% Albumin in the Presence of Brain Alone  
or in Combination with 200 mM Ascorbate

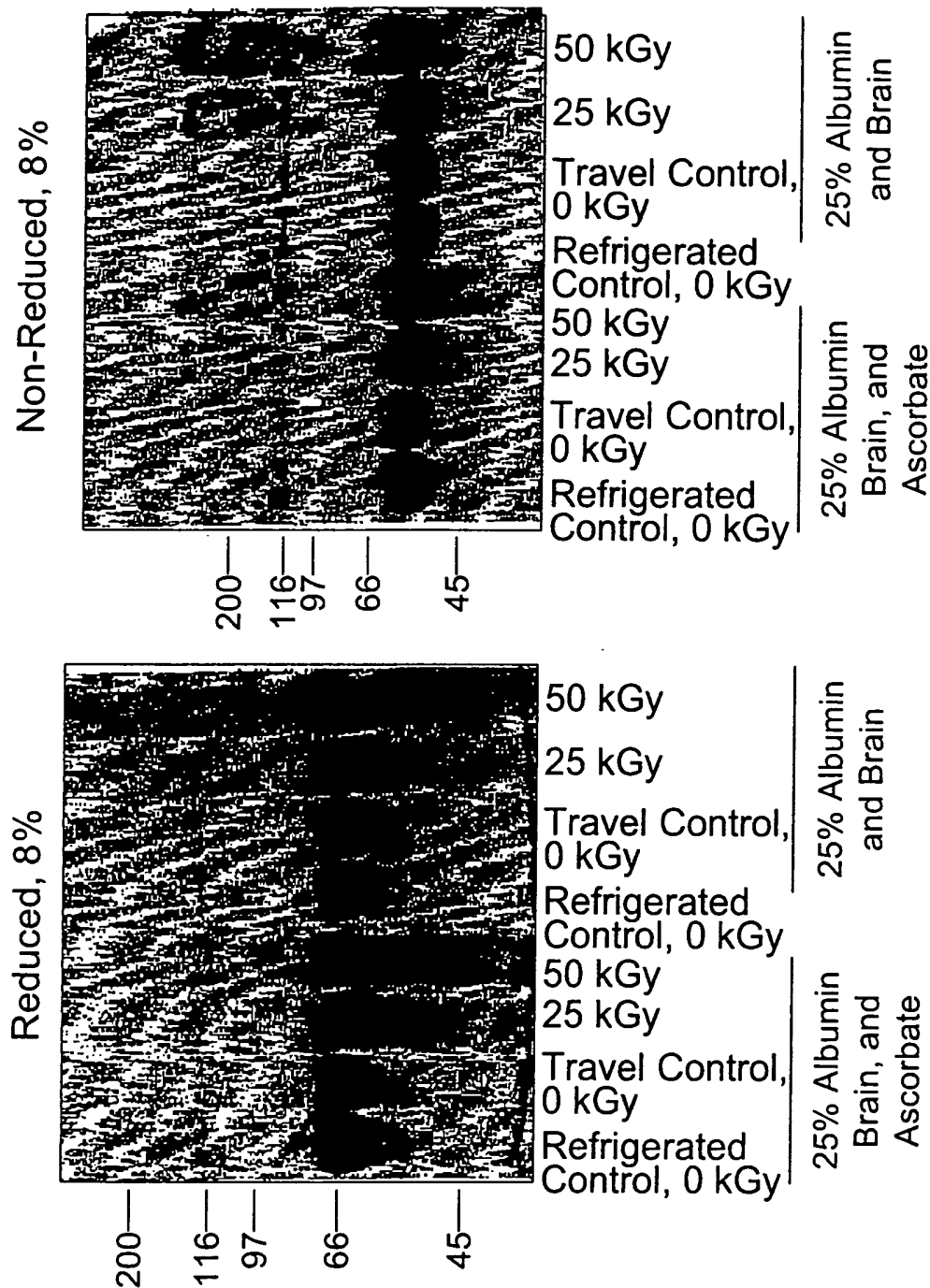


FIG. 33A

Gamma Irradiation (to 25 and 50 kGy)  
of 25% Albumin in the Presence  
or Absence of 200 mM Ascorbate

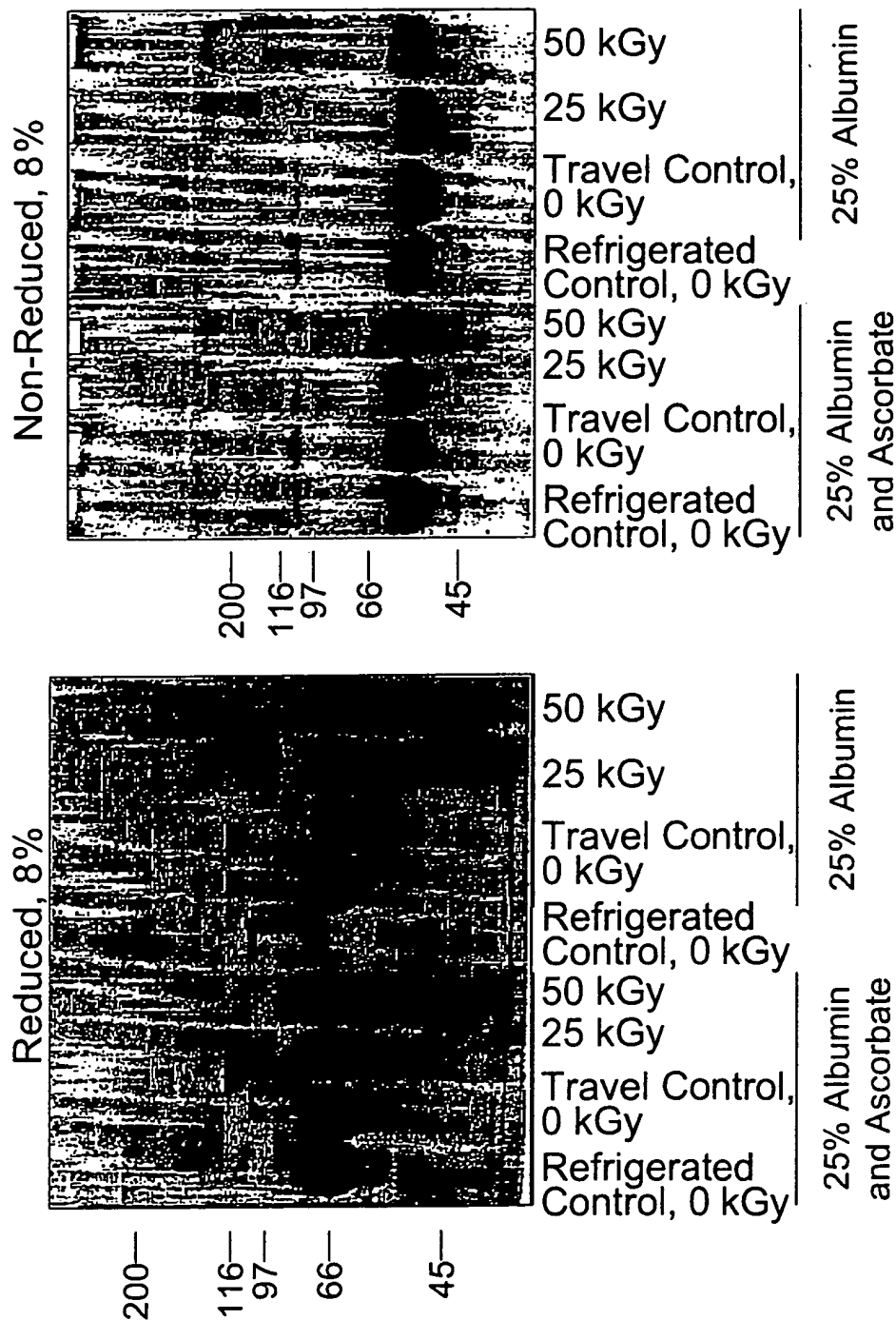


FIG. 33B

78/113

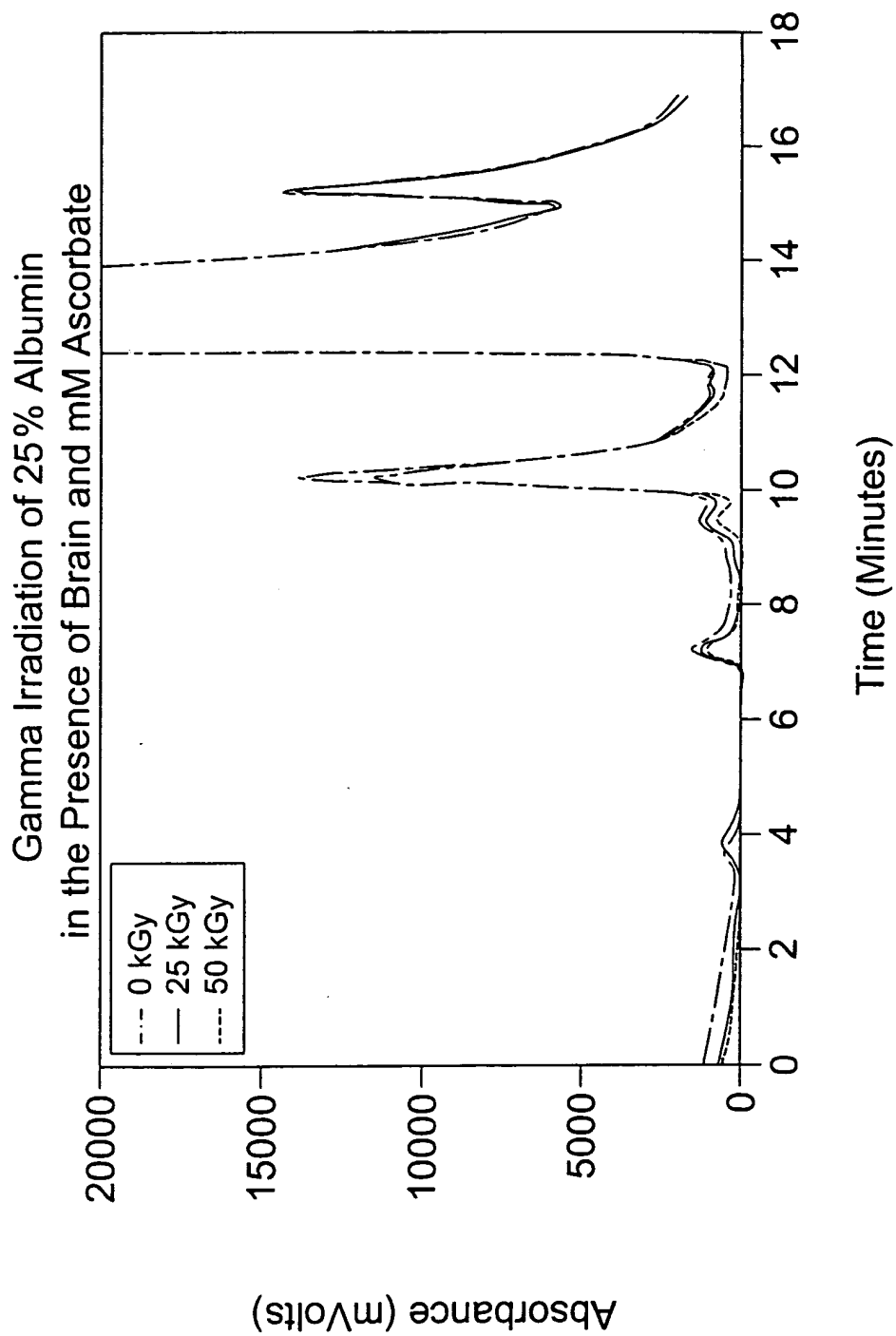


FIG. 33C

79/113

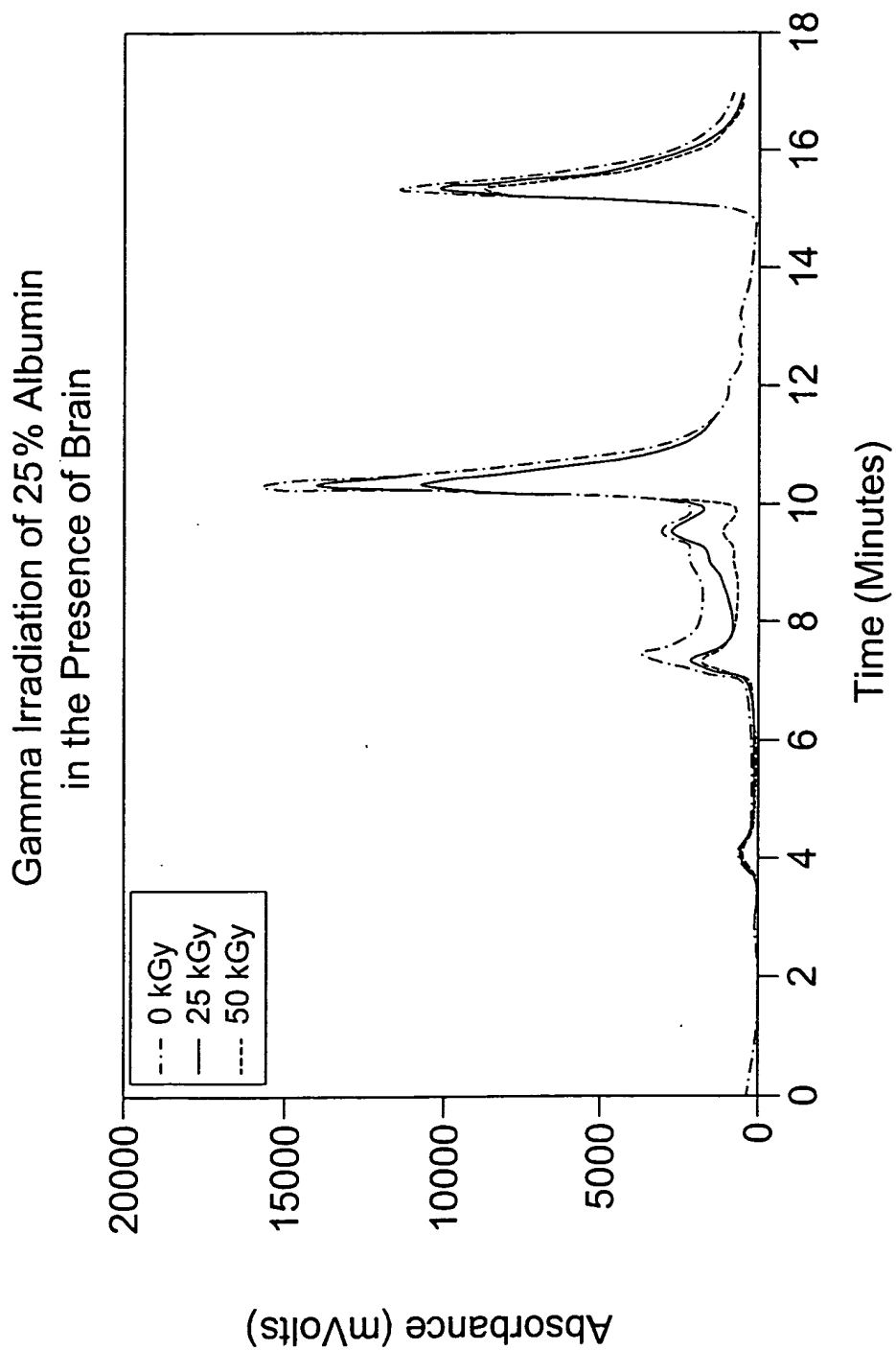


FIG. 33D

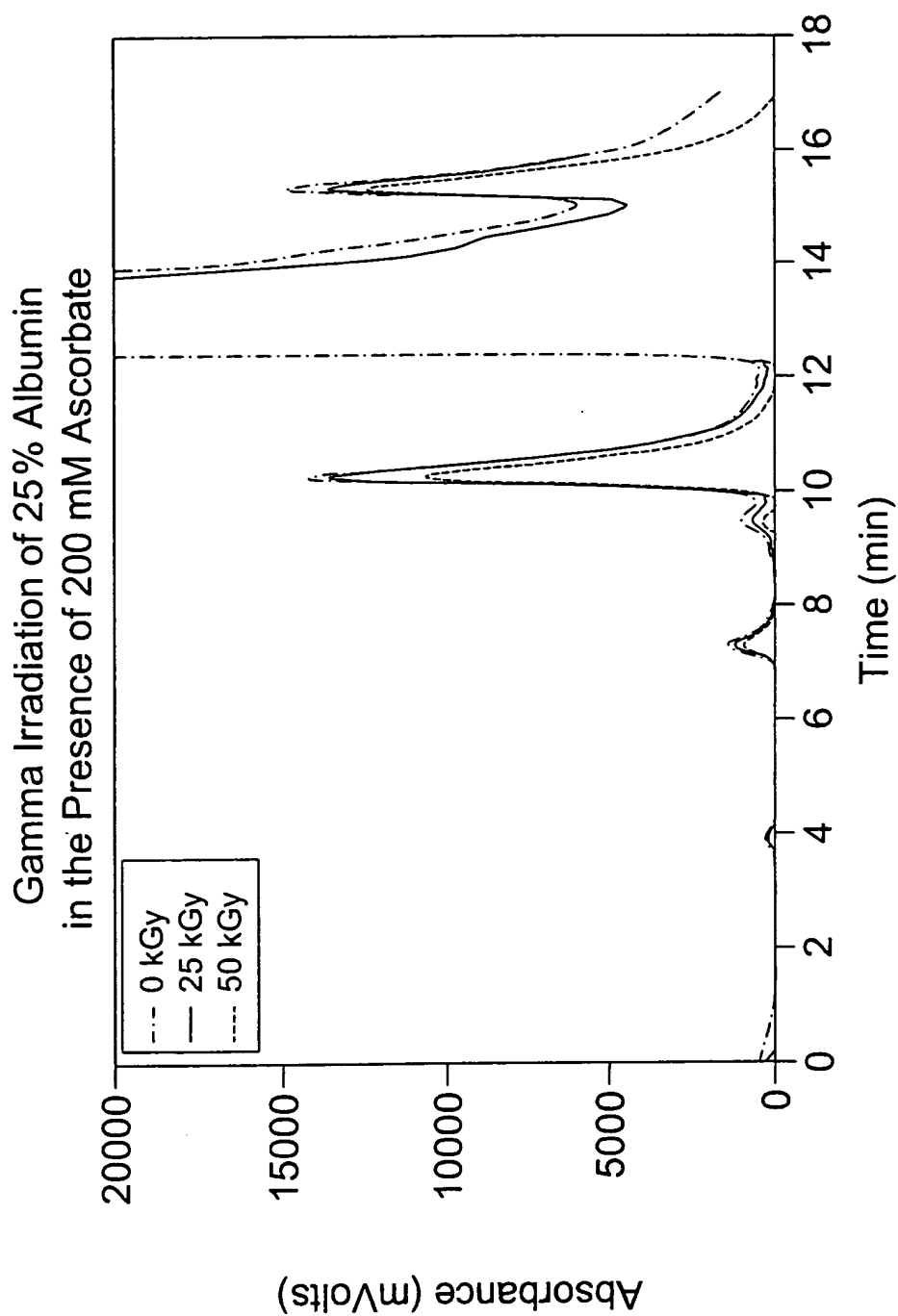


FIG. 33E





81/113

# Gamma Irradiation of 25% Albumin

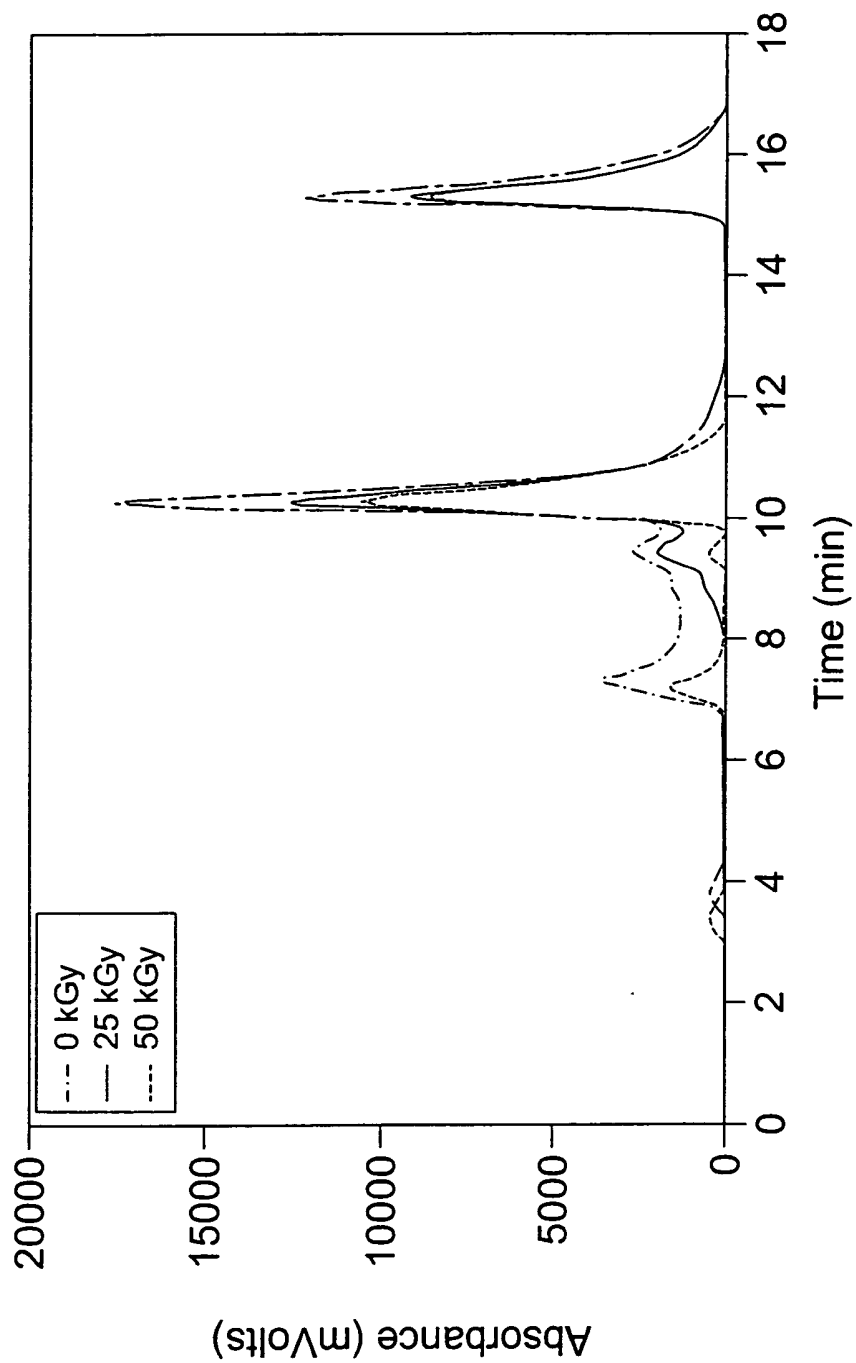


FIG. 33F

Gamma Irradiation of Lyophilized Albumin

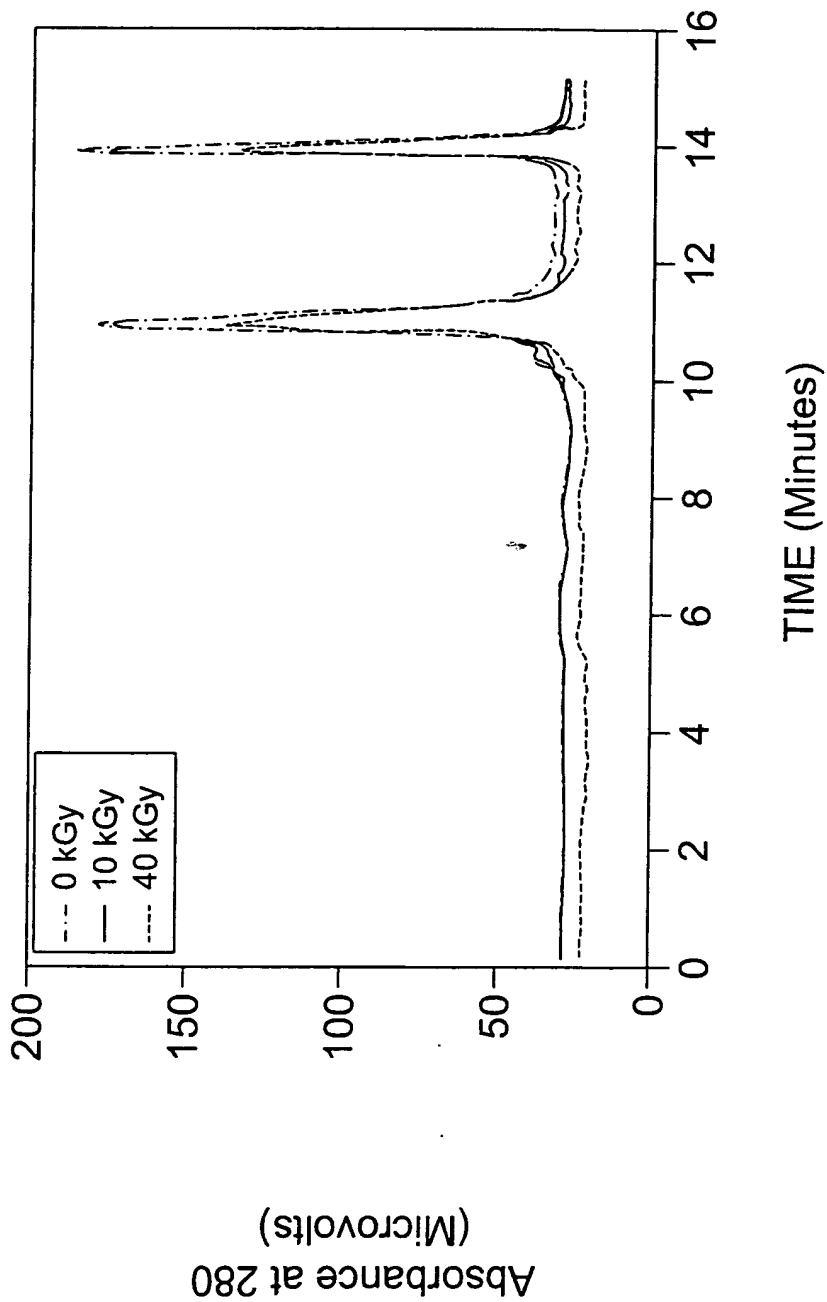


FIG. 34A

Gamma Irradiation of Liquid Albumin

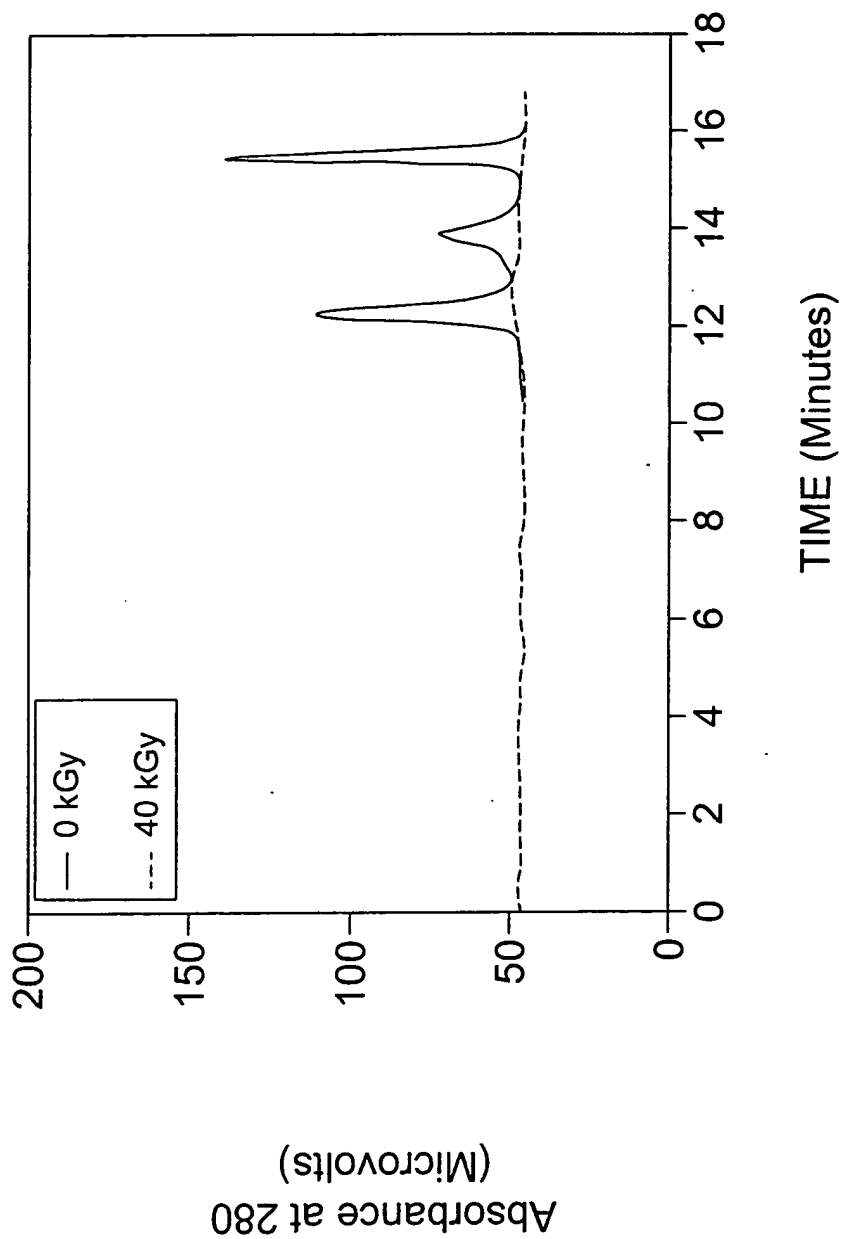
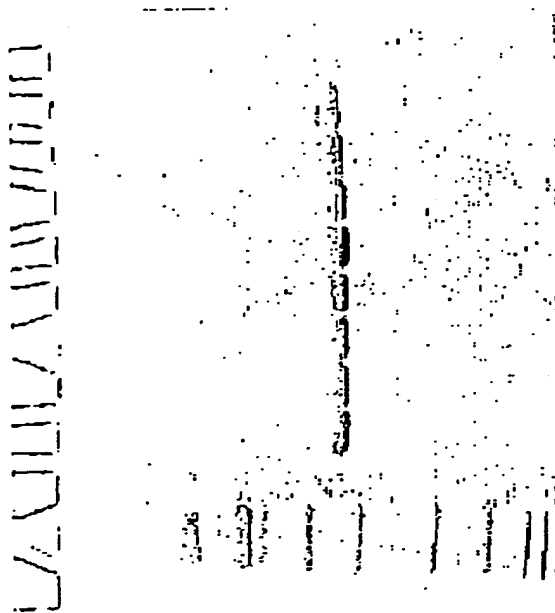


FIG. 34B



84/113

25% Albumin - Non-Reduced



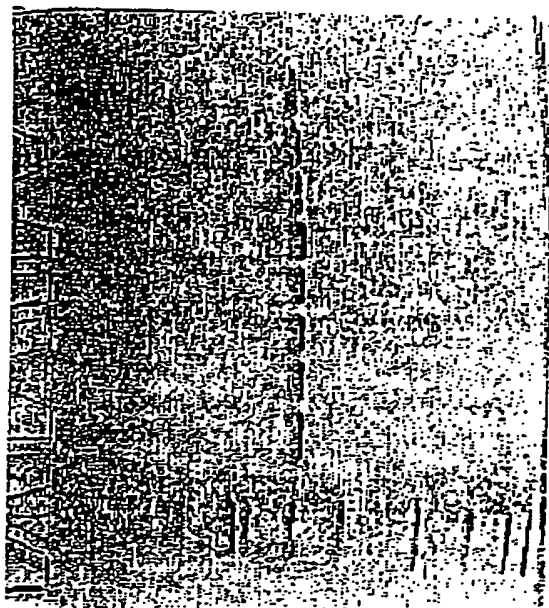
Std	Lane	Sample
Kd	1	Empty
	2	Broad Range Std. (BioRad)
	3	Empty
200	4	0 Kgy (Control) Box 3C (+ Ar)
116	5	18.0 Kgy ( $\approx 0.91$ Kgy/hr) Box 1 (+ Ar)
97	6	23.0 Kgy ( $\approx 0.92$ Kgy/hr) Box 2 (+ Ar)
66	7	30.4 Kgy ( $\approx 1.01$ Kgy/hr) Box 3 (+ Ar)
45	8	0 Kgy (Control) Box 3C (- Ar)
31	9	18.0 Kgy ( $\approx 0.91$ Kgy/hr) Box 1 (- Ar)
21.5	10	23.0 Kgy ( $\approx 0.92$ Kgy/hr) Box 2 (- Ar)
14.4	11	30.4 Kgy ( $\approx 1.01$ Kgy/hr) Box 3 (- Ar)
	12	Empty

FIG. 35A



85/113

25% Albumin - Reduced



1	2	3	4	5	6	7	8	9	10	11	12
Std	Lane Sample										
Kd	1	2	3	4	5	6	7	8	9	10	11
	Empty	Broad Range Std. (BioRad)	Empty	0 Kgy (Control) Box 3C (+ Ar)	18.0 Kgy (~0.91 Kgy/hr) Box 1 (+ Ar)	23.0 Kgy (~0.92 Kgy/hr) Box 2 (+ Ar)	30.4 Kgy (~1.01 Kgy/hr) Box 3 (+ Ar)	0 Kgy (Control) Box 3C (- Ar)	18.0 Kgy (~0.91 Kgy/hr) Box 1 (- Ar)	23.0 Kgy (~0.92 Kgy/hr) Box 2 (- Ar)	30.4 Kgy (~1.01 Kgy/hr) Box 3 (- Ar)
200											
116											
97											
66											
45											
31											
21.5											
14.4											

FIG. 35B

Gamma Irradiation of Powder PPF at -20°C  
 Reduced

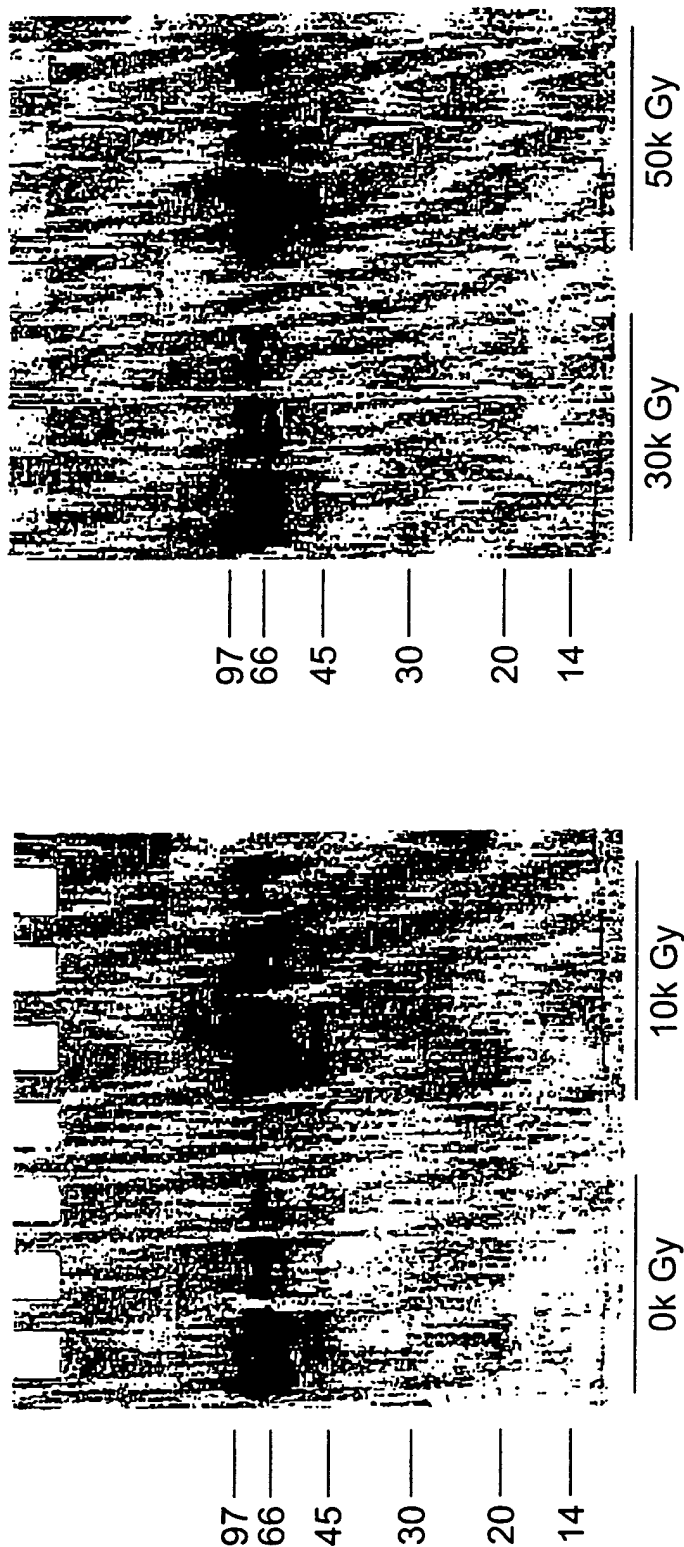


FIG. 36A

Gamma Irradiation of Powder PPF at -20°C

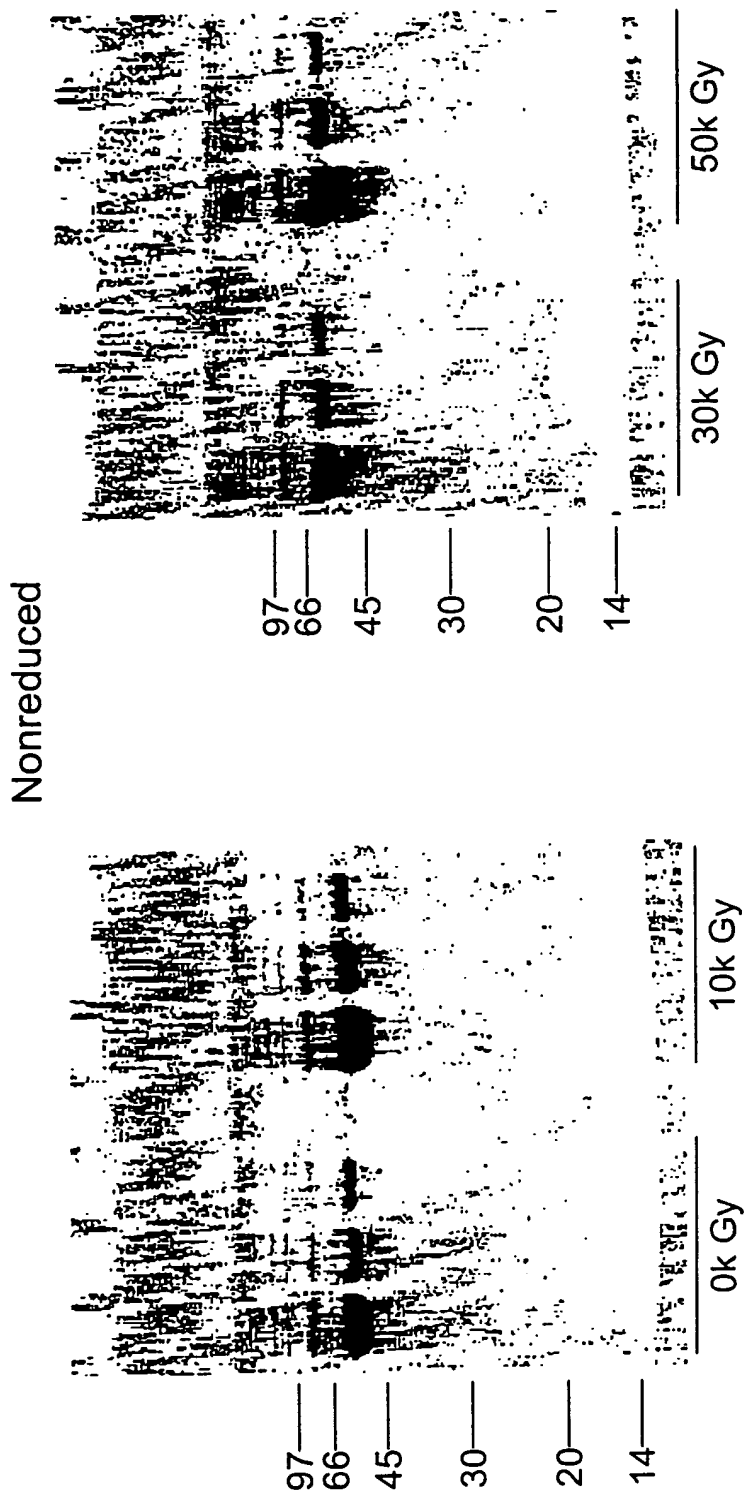


FIG. 36B



88/113

# Gamma Irradiation of PPF

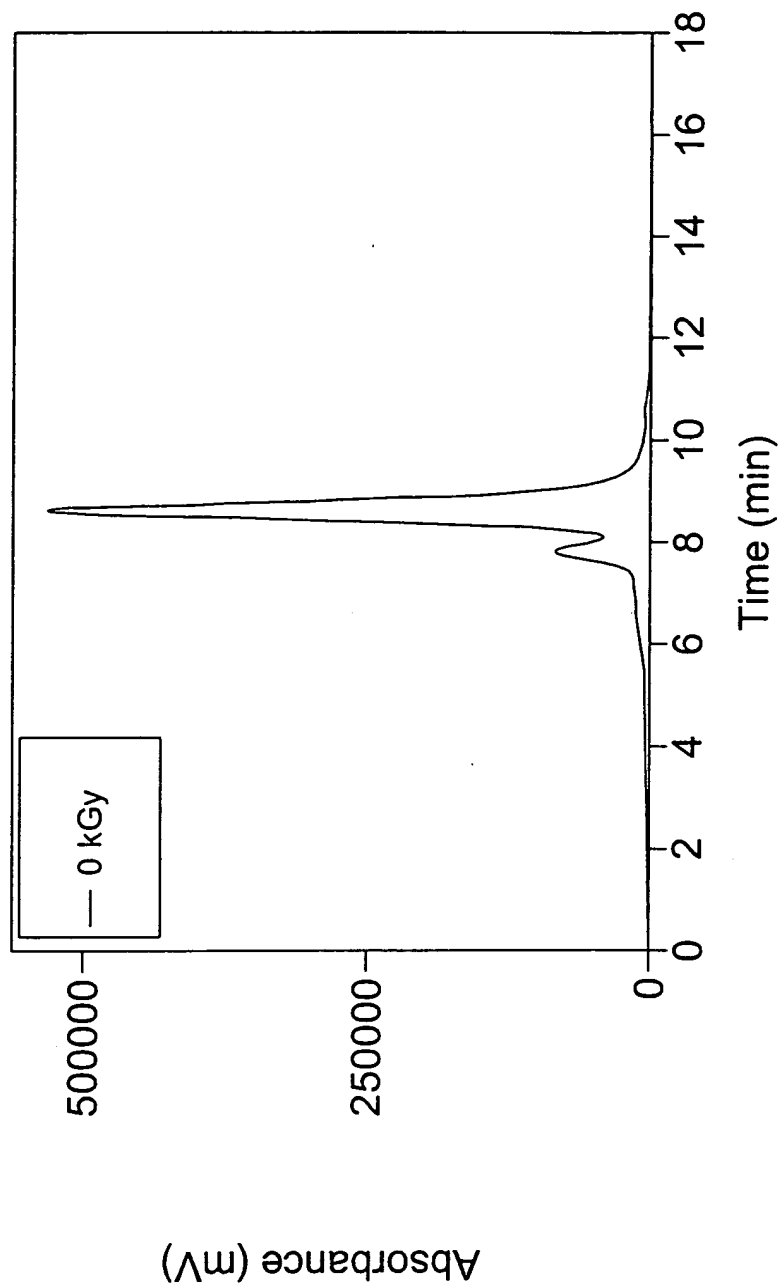


FIG. 36C



Gamma Irradiation of PPF

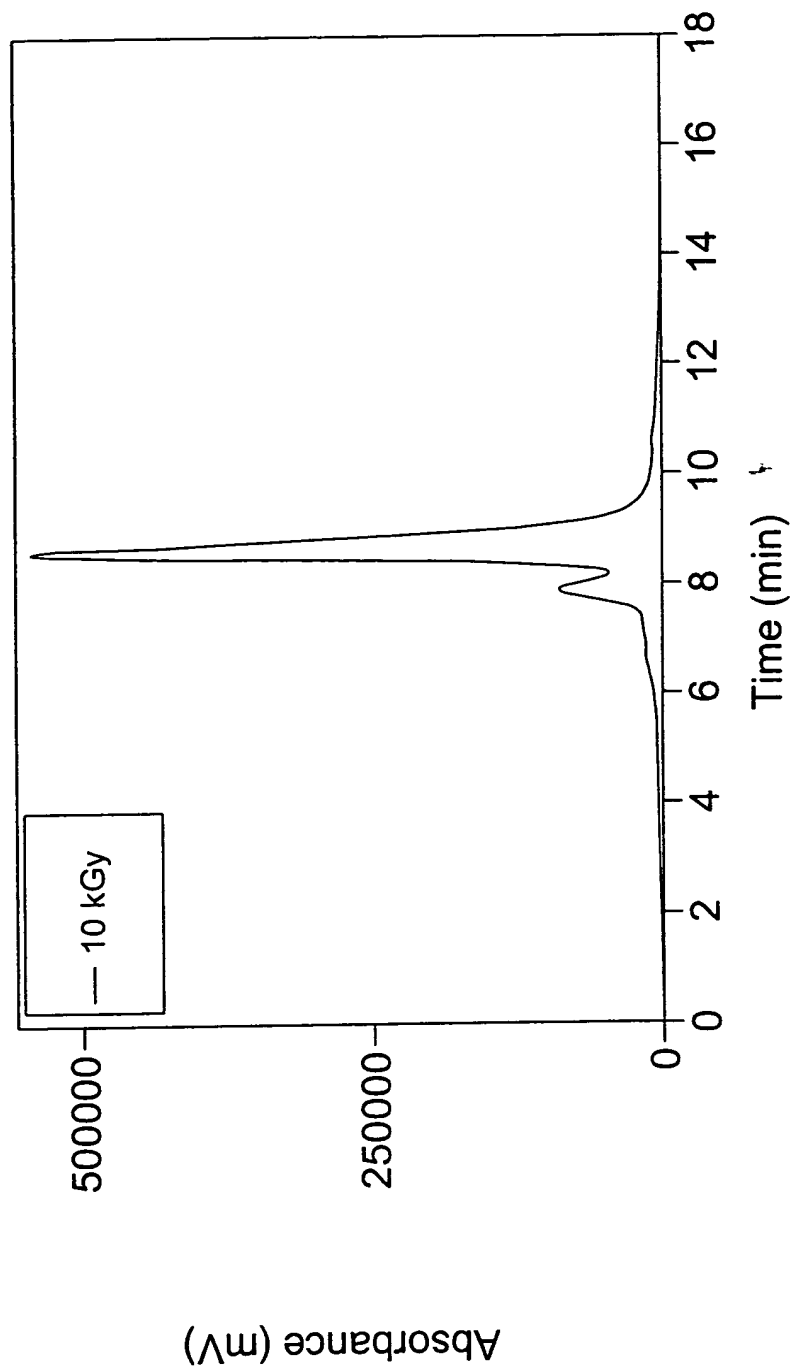


FIG. 36D



90/113

# Gamma Irradiation of Powder PPF

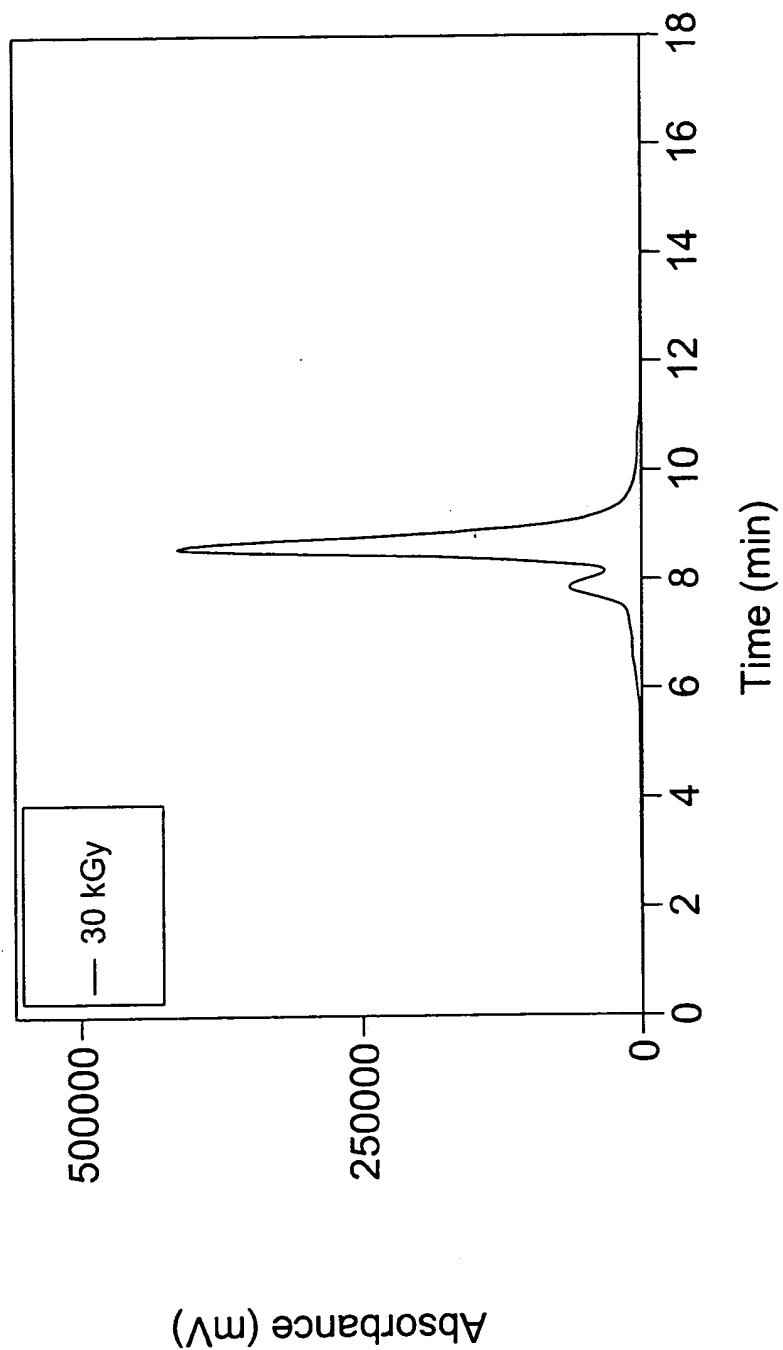


FIG. 36E



91/113

# Gamma Irradiation of Powder PPF

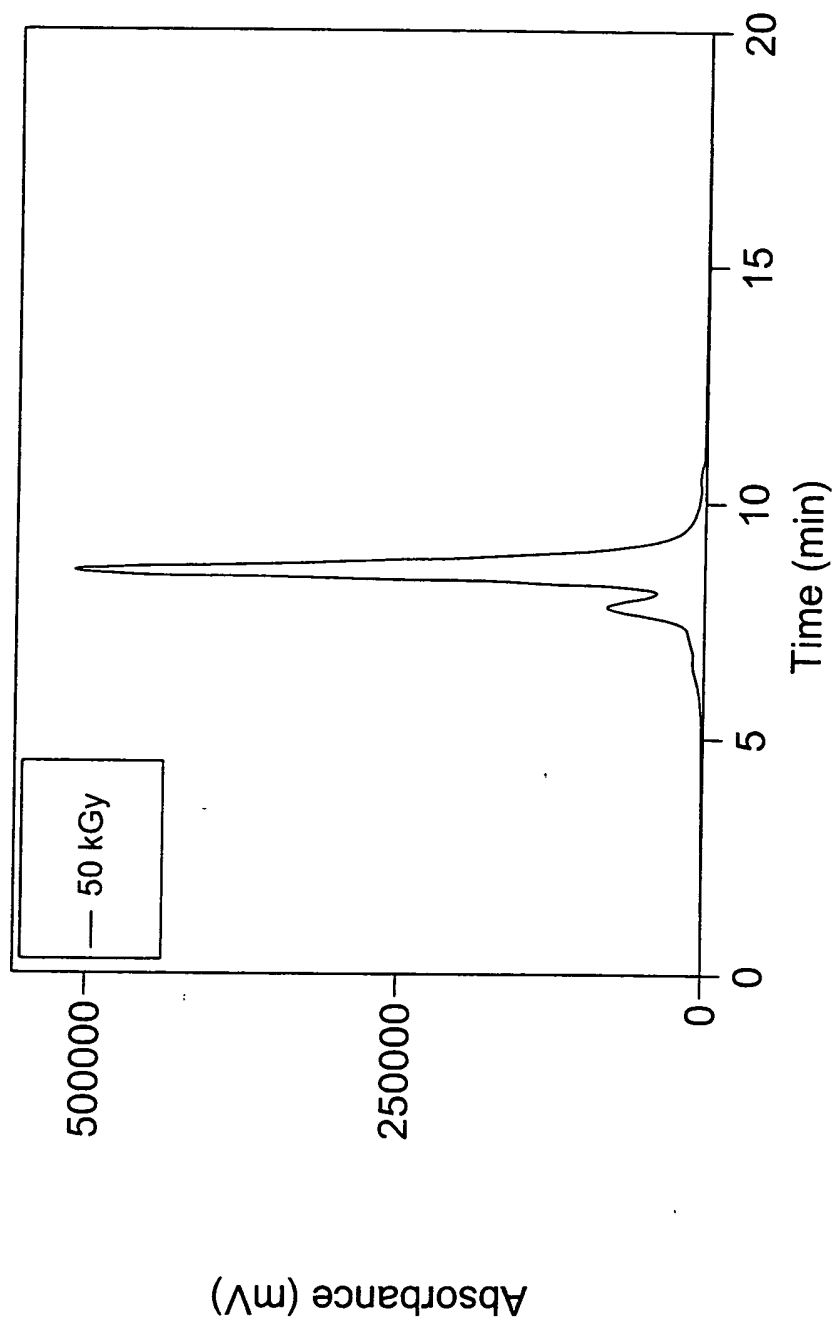


FIG. 36F



92/113

Gamma Irradiation of PPV in PPF by Irradiation at -80°C

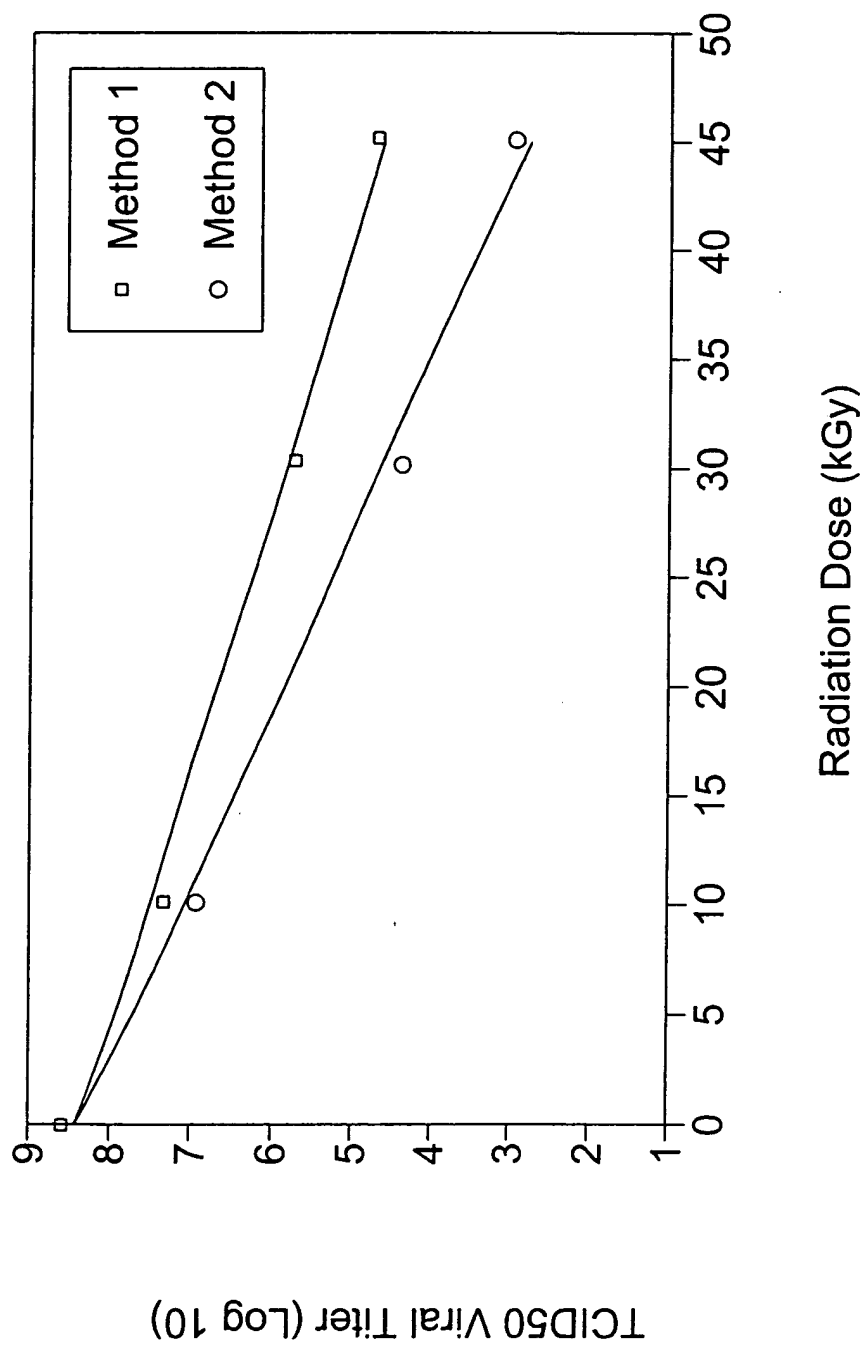


FIG. 37A

Gamma Irradiation of PPF By Method 2

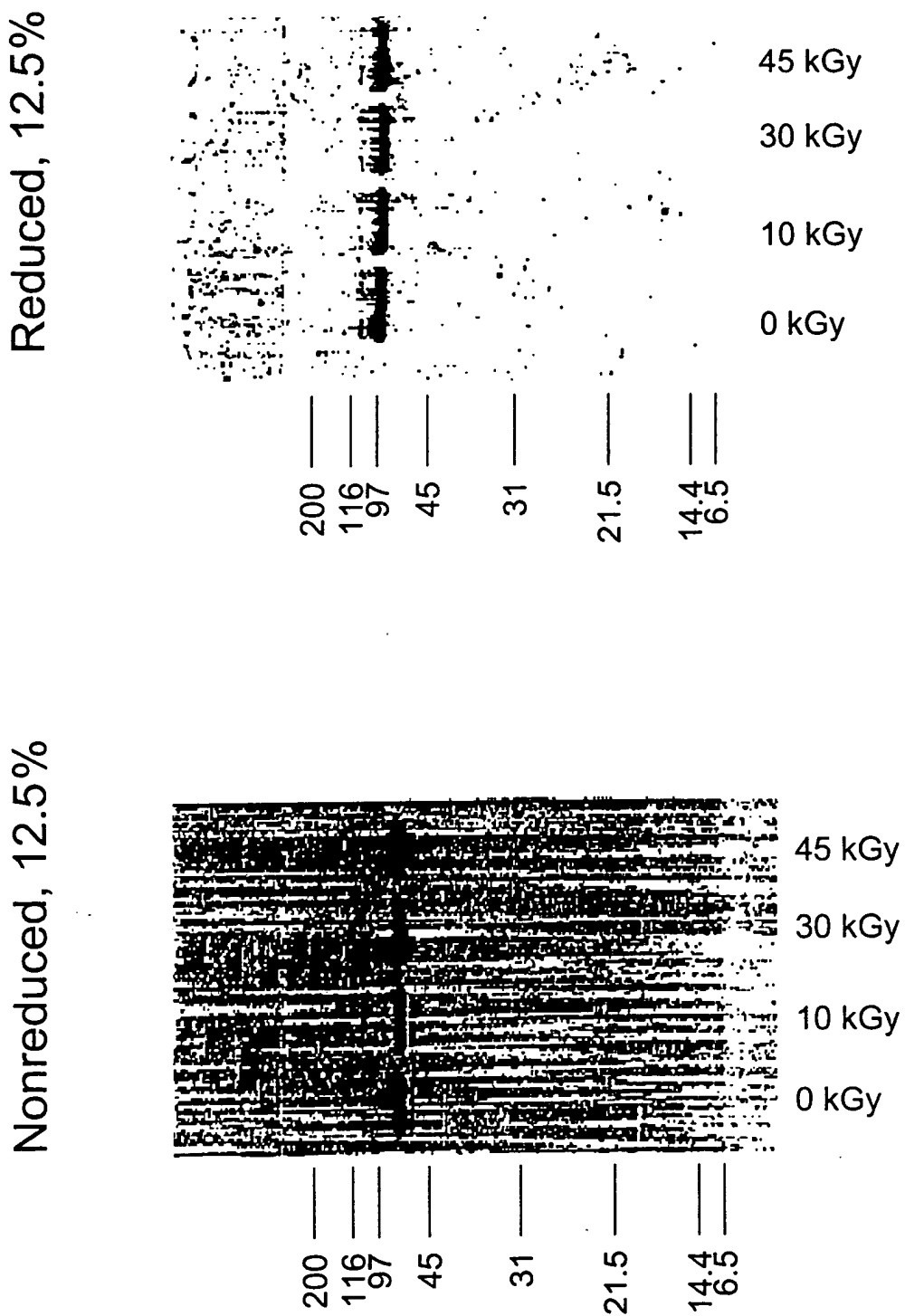


FIG. 37B

Gamma Irradiation of PPF By Method 1

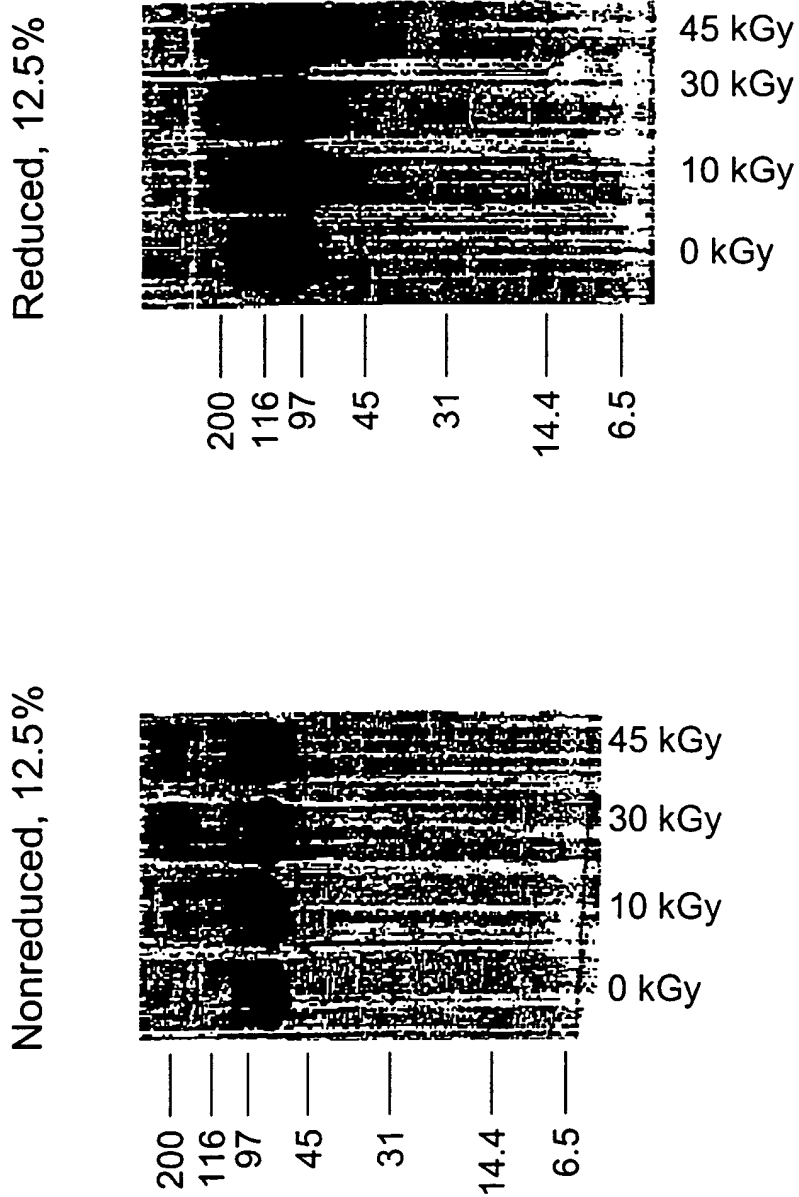


FIG. 37C



95/113

# Gamma Irradiation of FVIII

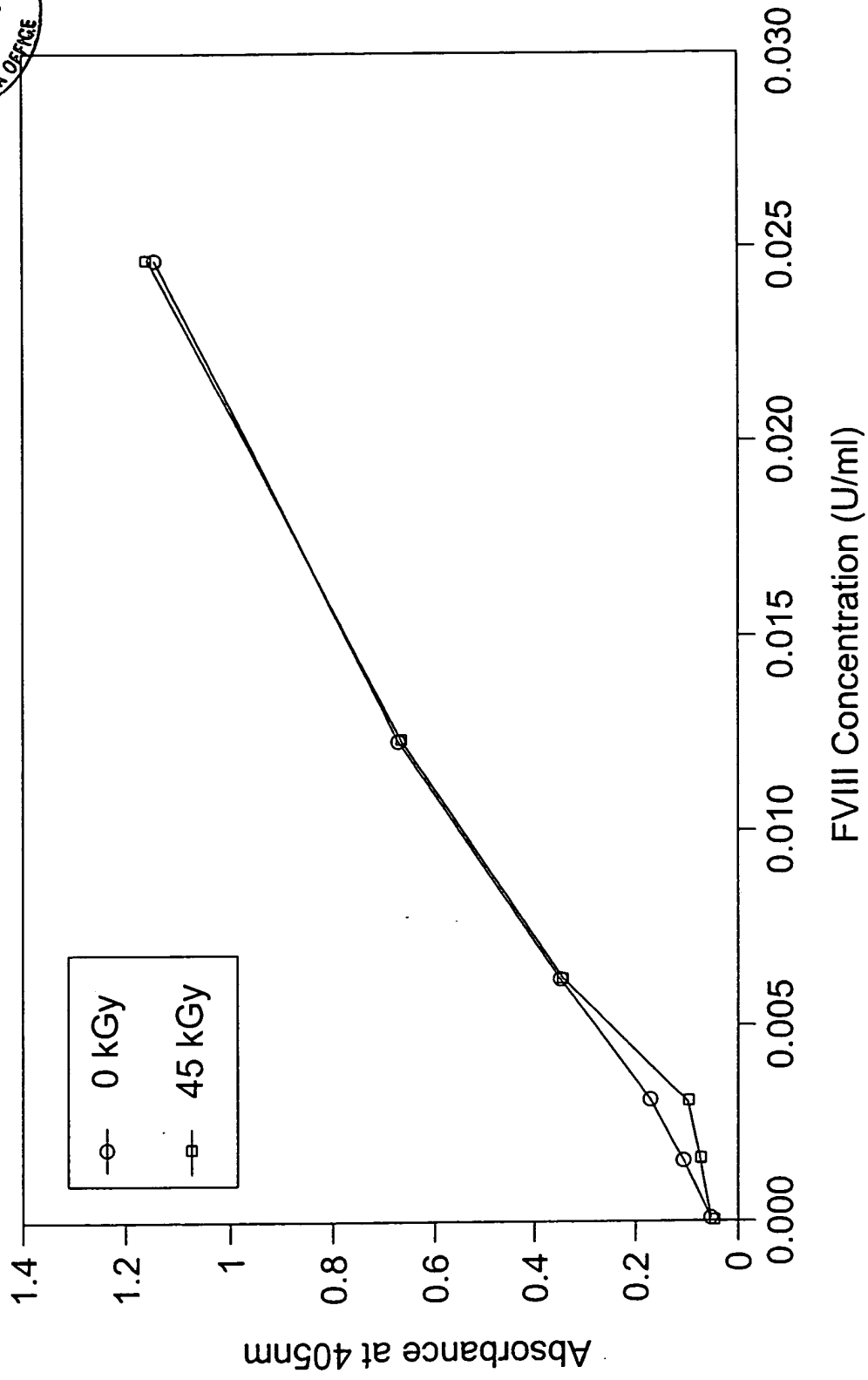


FIG. 38



96/113

Gamma Irradiation of Lyophilized Trypsin  
in the Absence of Ascorbate

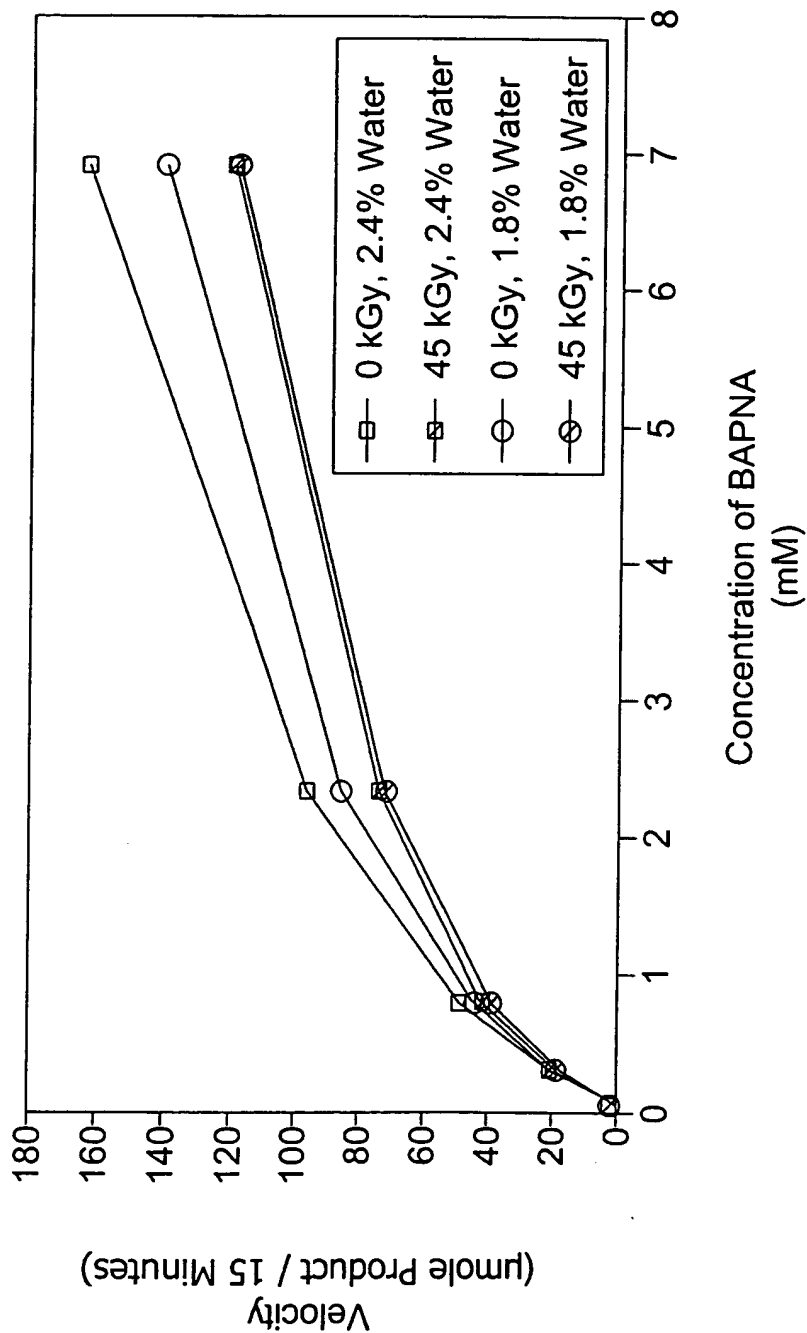


FIG. 39A





97/113

Gamma Irradiation of Lyophilized Trypsin  
in the Presence of 100 mM Ascorbate

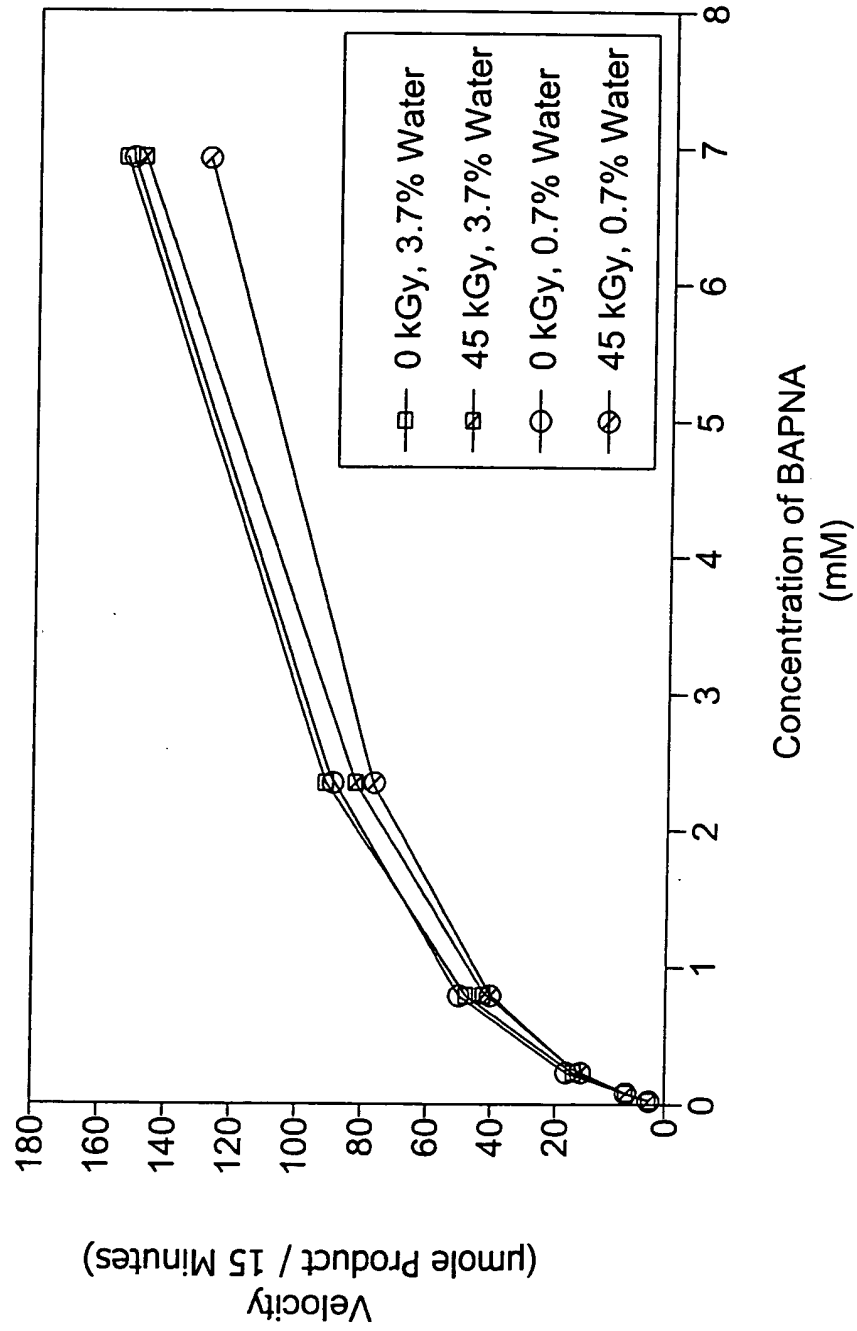


FIG. 39B

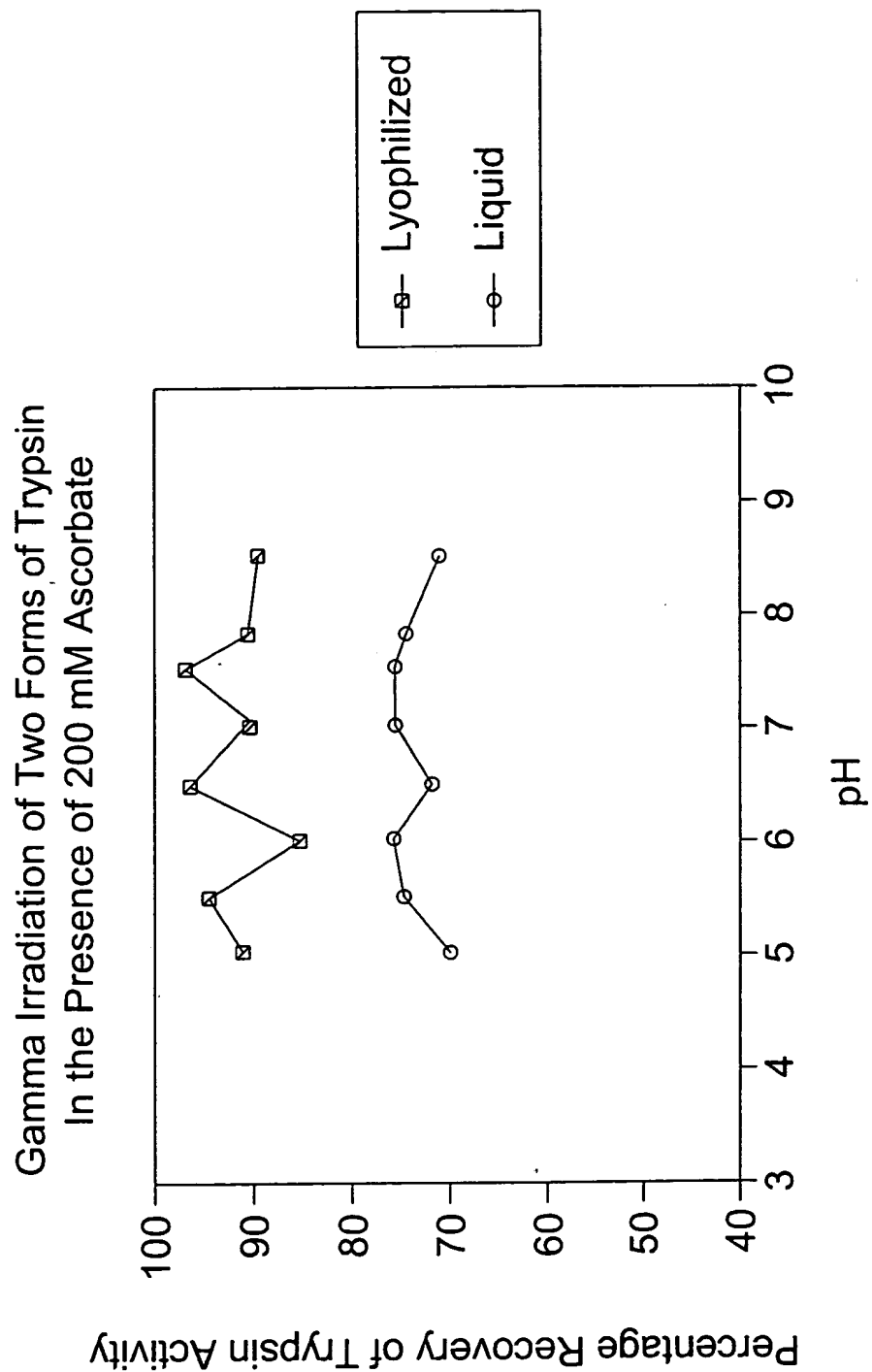


FIG. 40

Gamma Irradiation of Lyophilized Trypsin  
In the Absence of Ascorbate

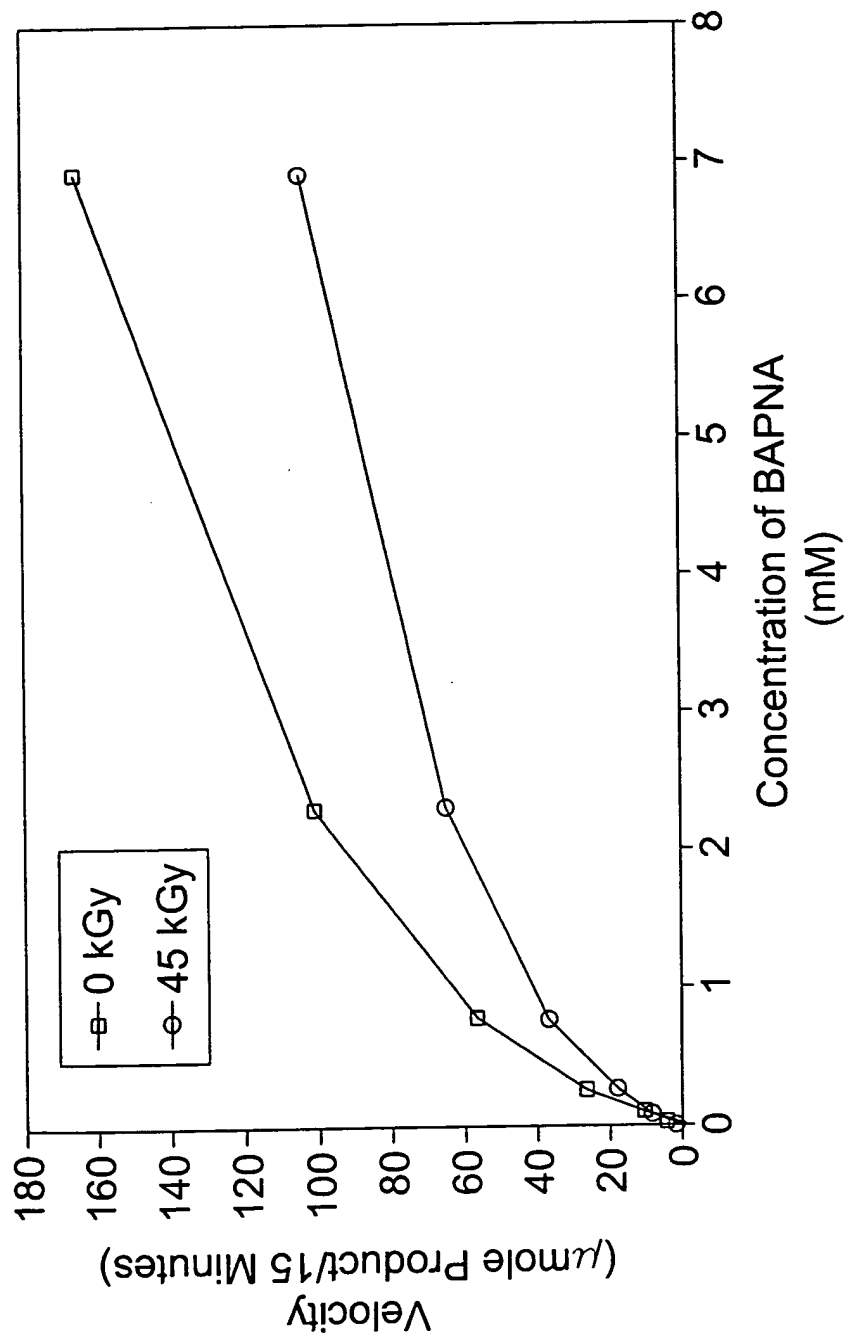


FIG. 41A

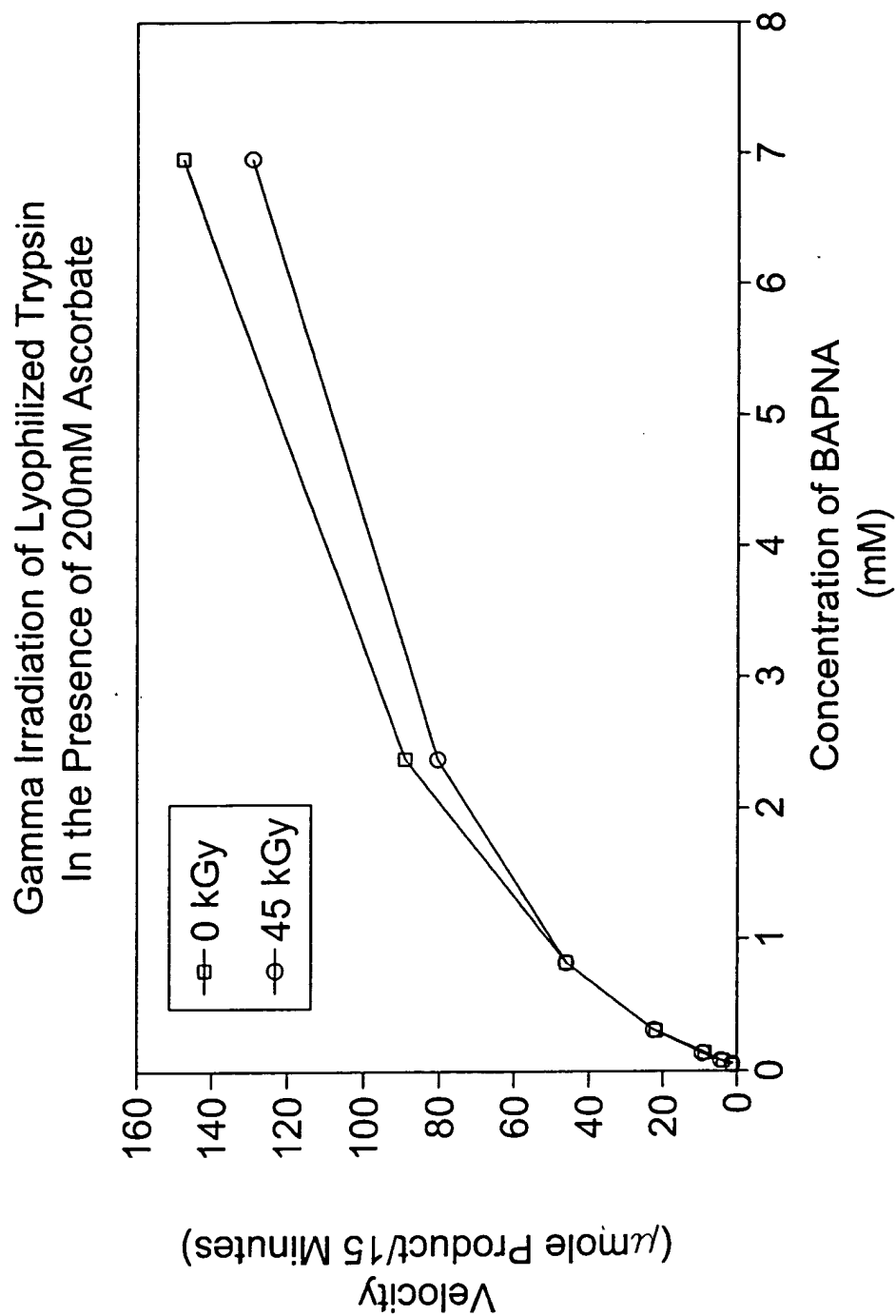


FIG. 41B

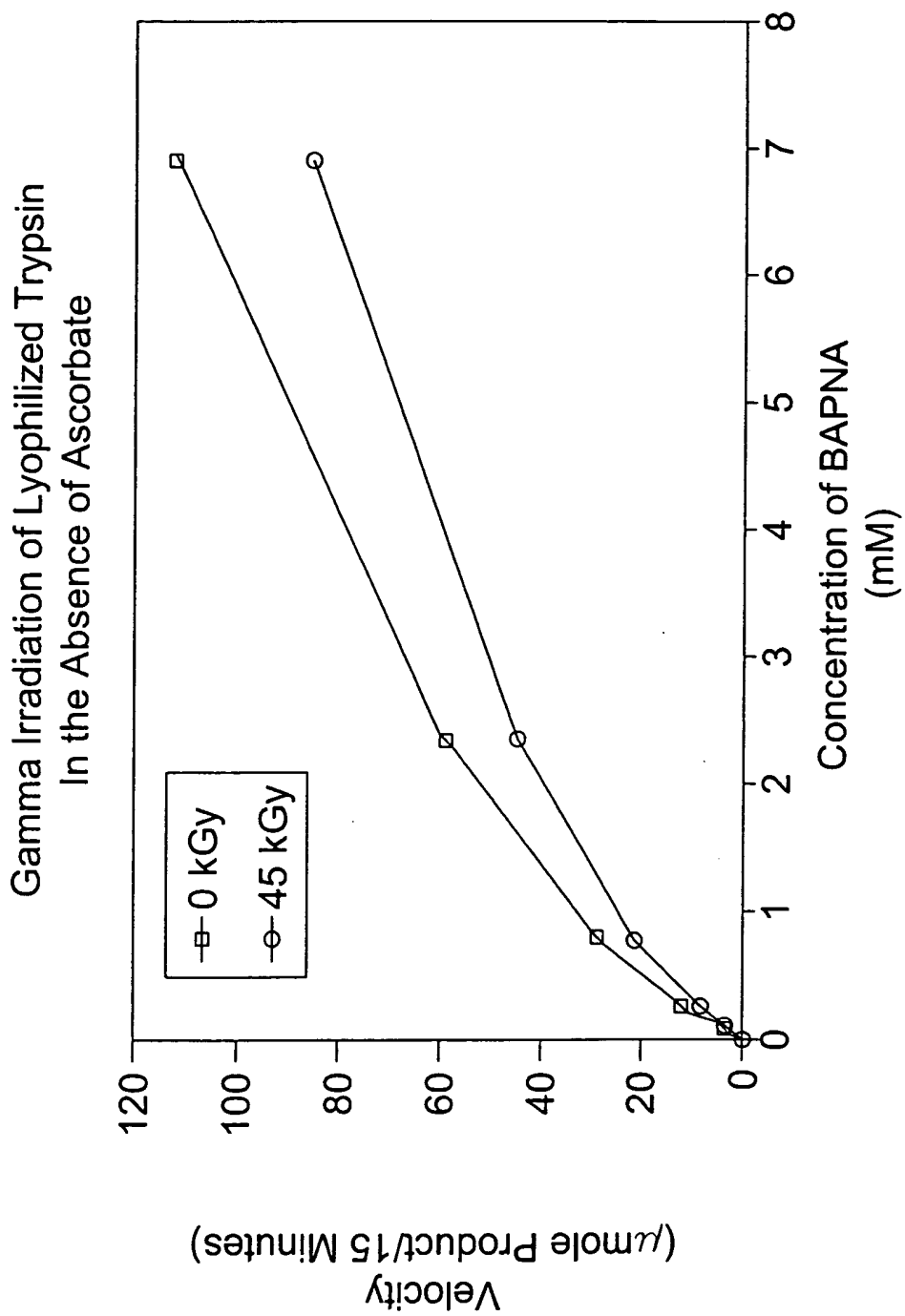


FIG. 42A

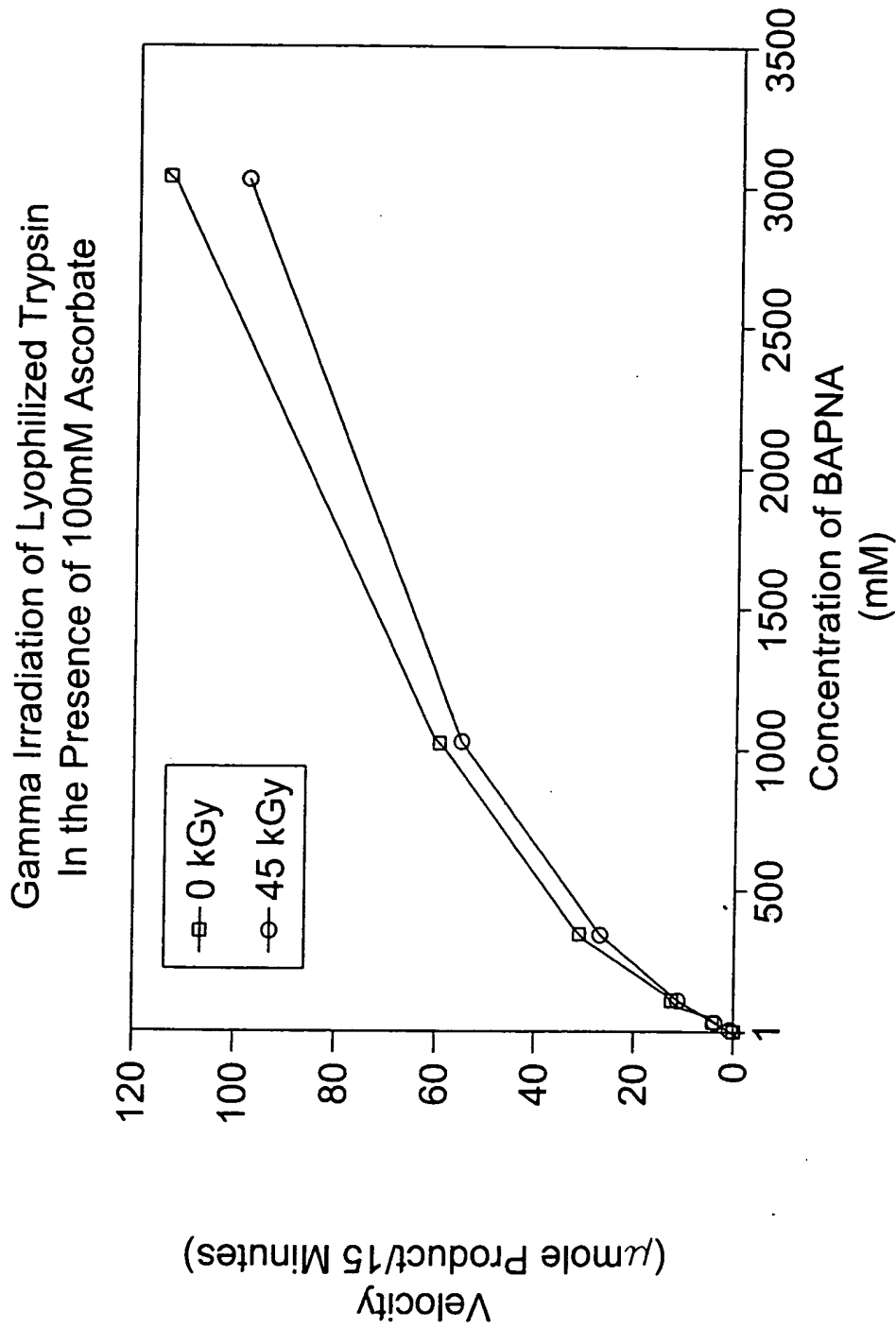


FIG. 42B

Gamma Irradiation of Lyophilized Trypsin  
In the Absence of Ascorbate

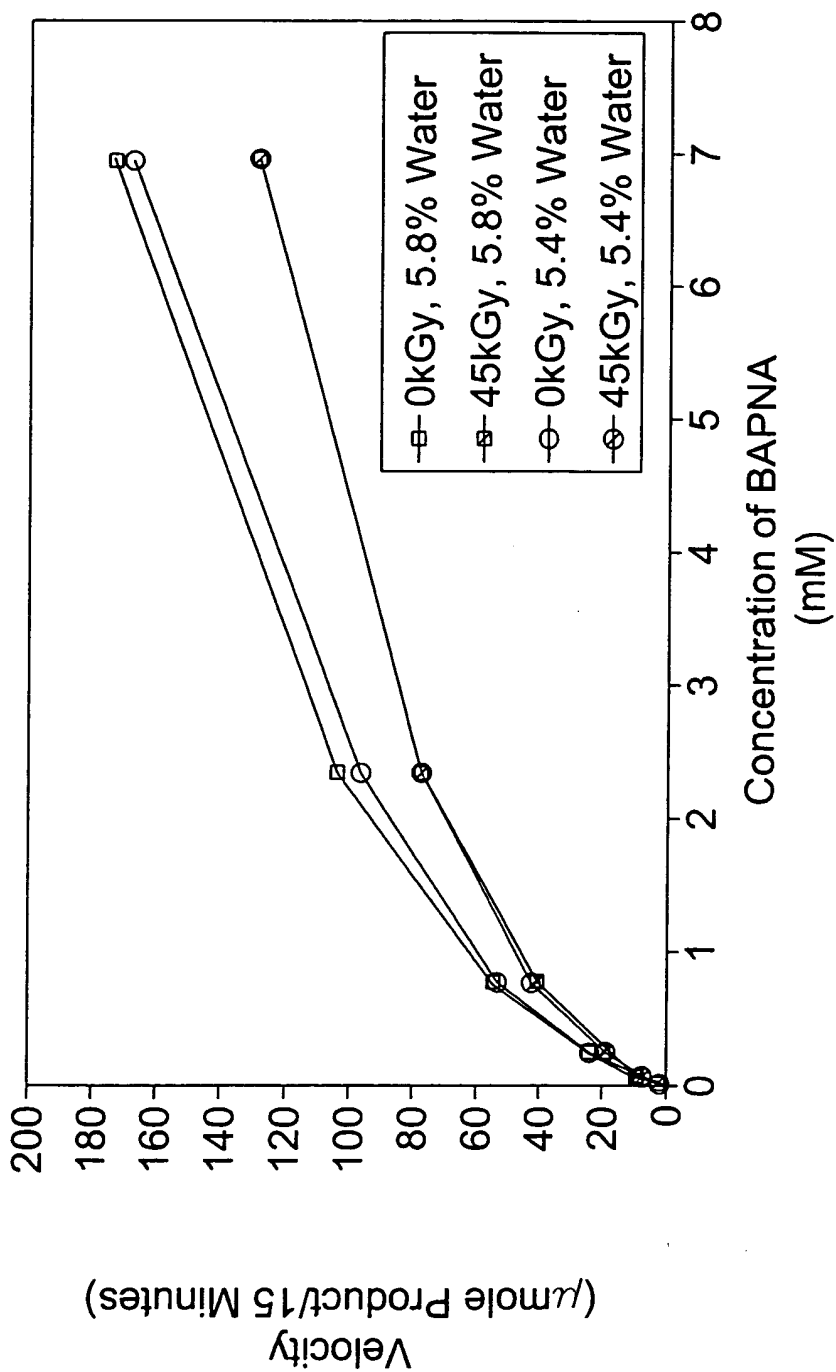


FIG. 43A



104/113

Gamma Irradiation of Lyophilized Trypsin  
In the Presence of 100 mM Ascorbate

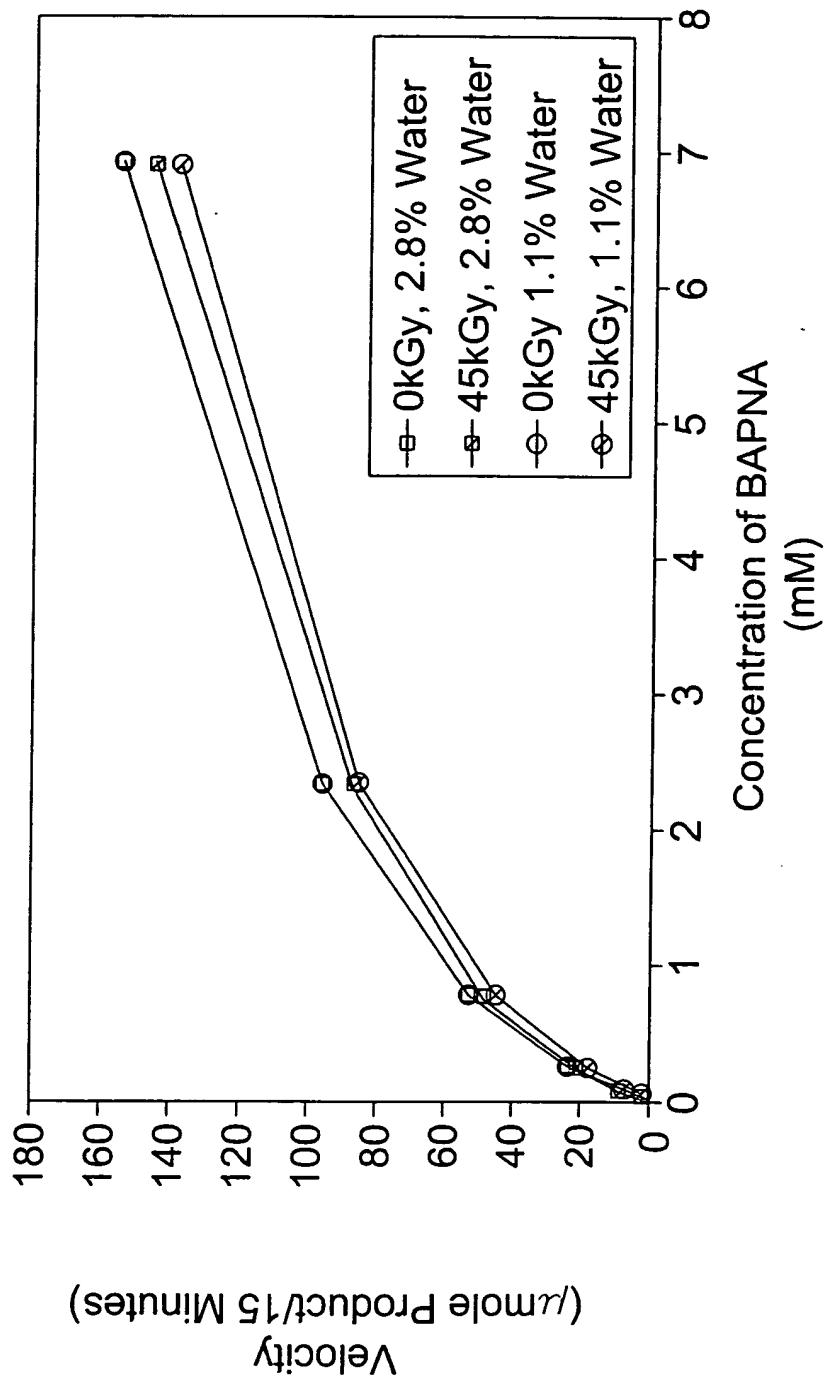


FIG. 43B



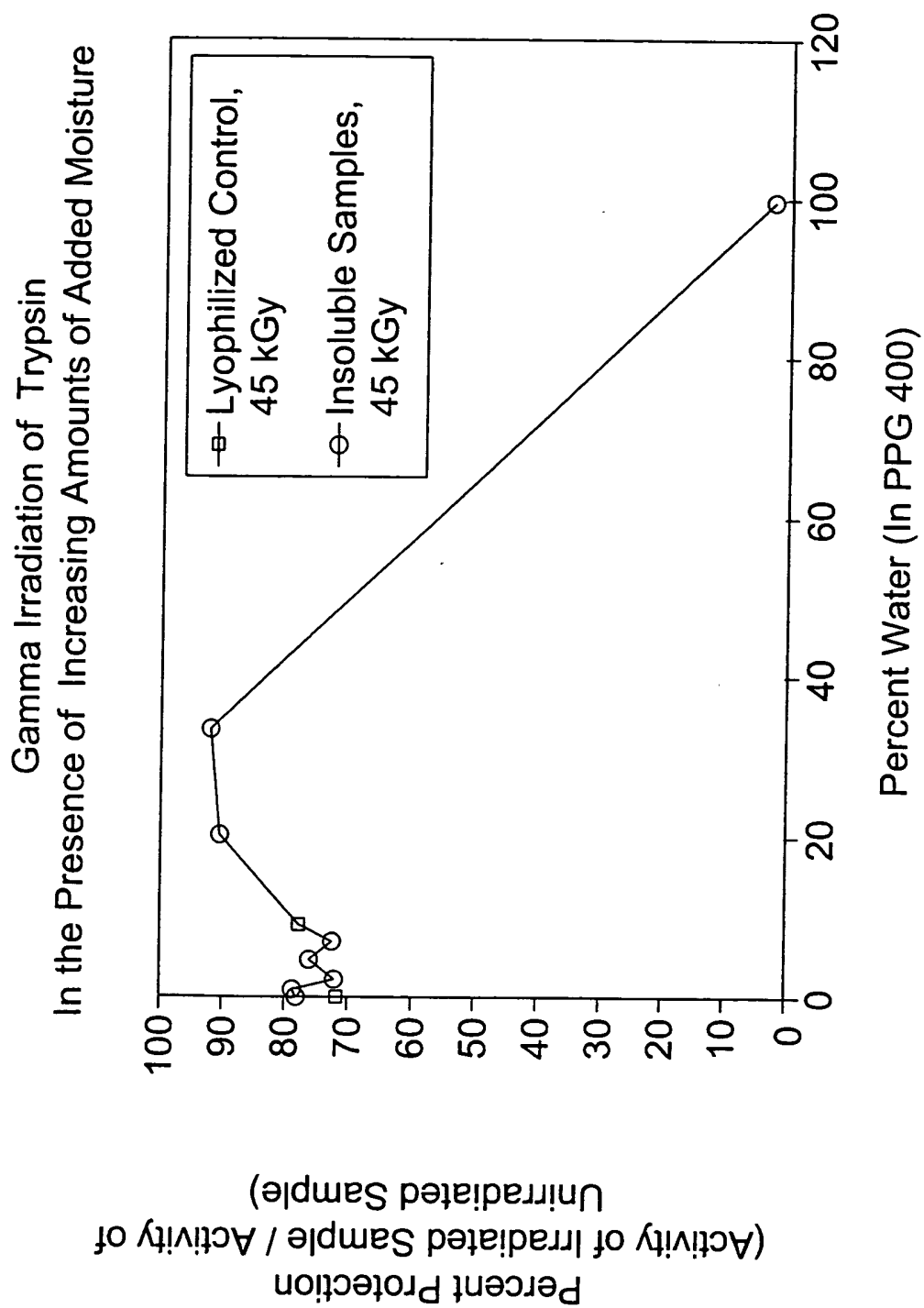


FIG. 44

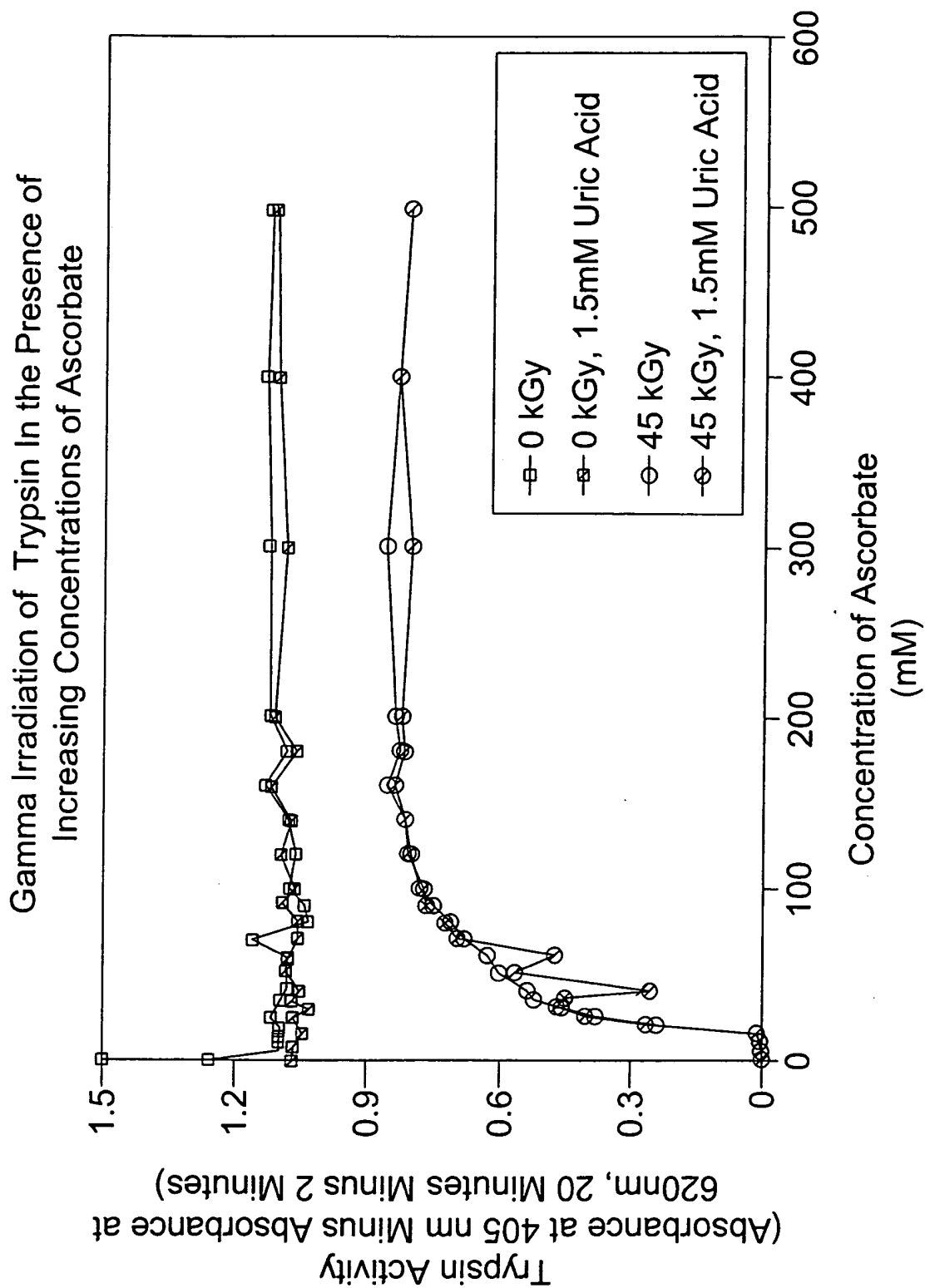


FIG. 45

107/113

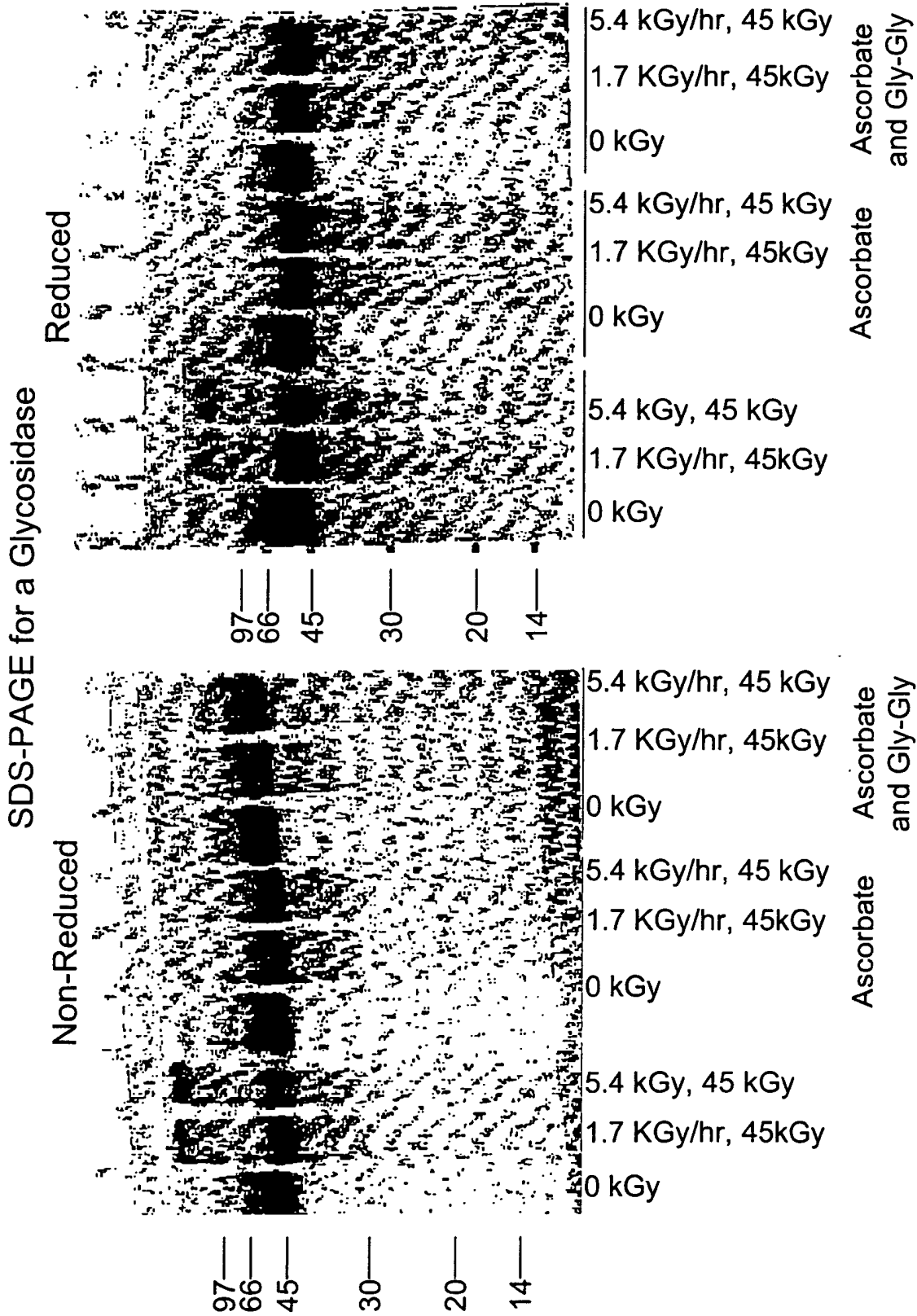


FIG. 46A

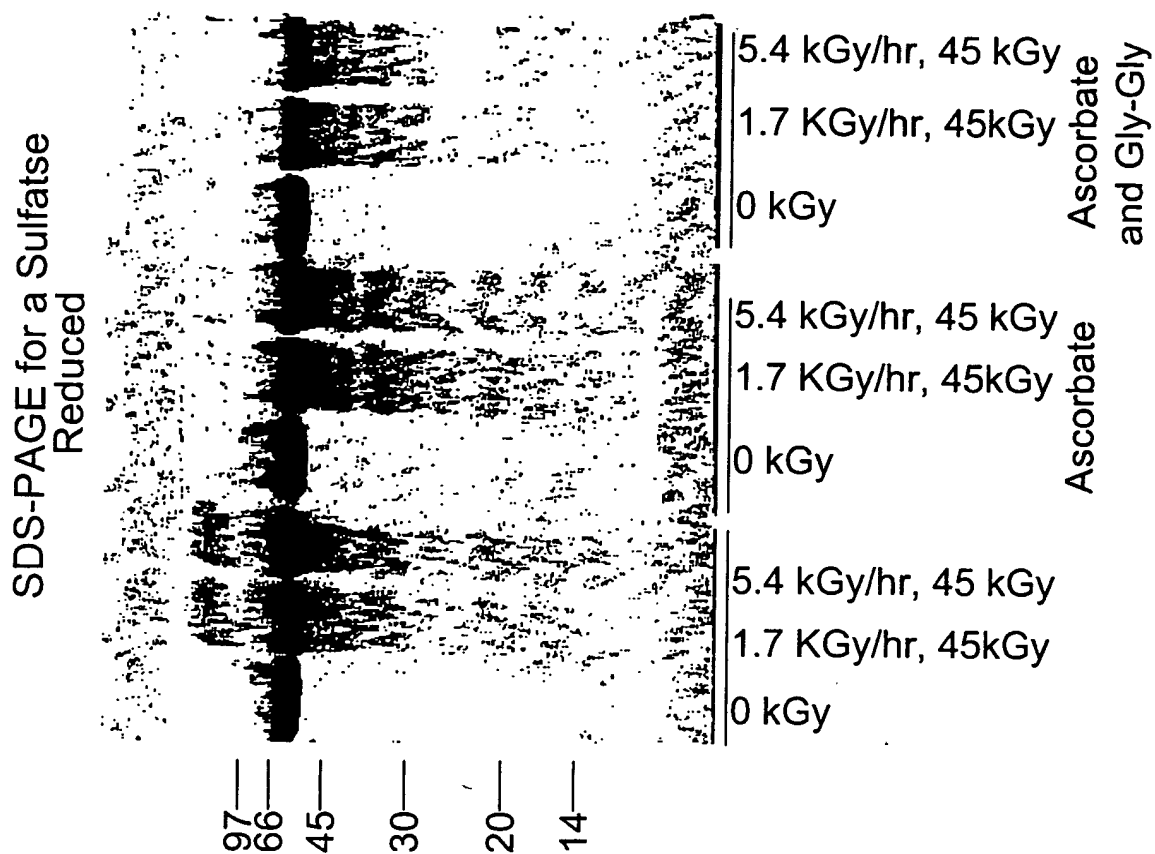


FIG. 46B

Gamma Irradiation of a Glycosidase In the Presence or Absence of Ascorbate Alone or in Combination with Gly-Gly

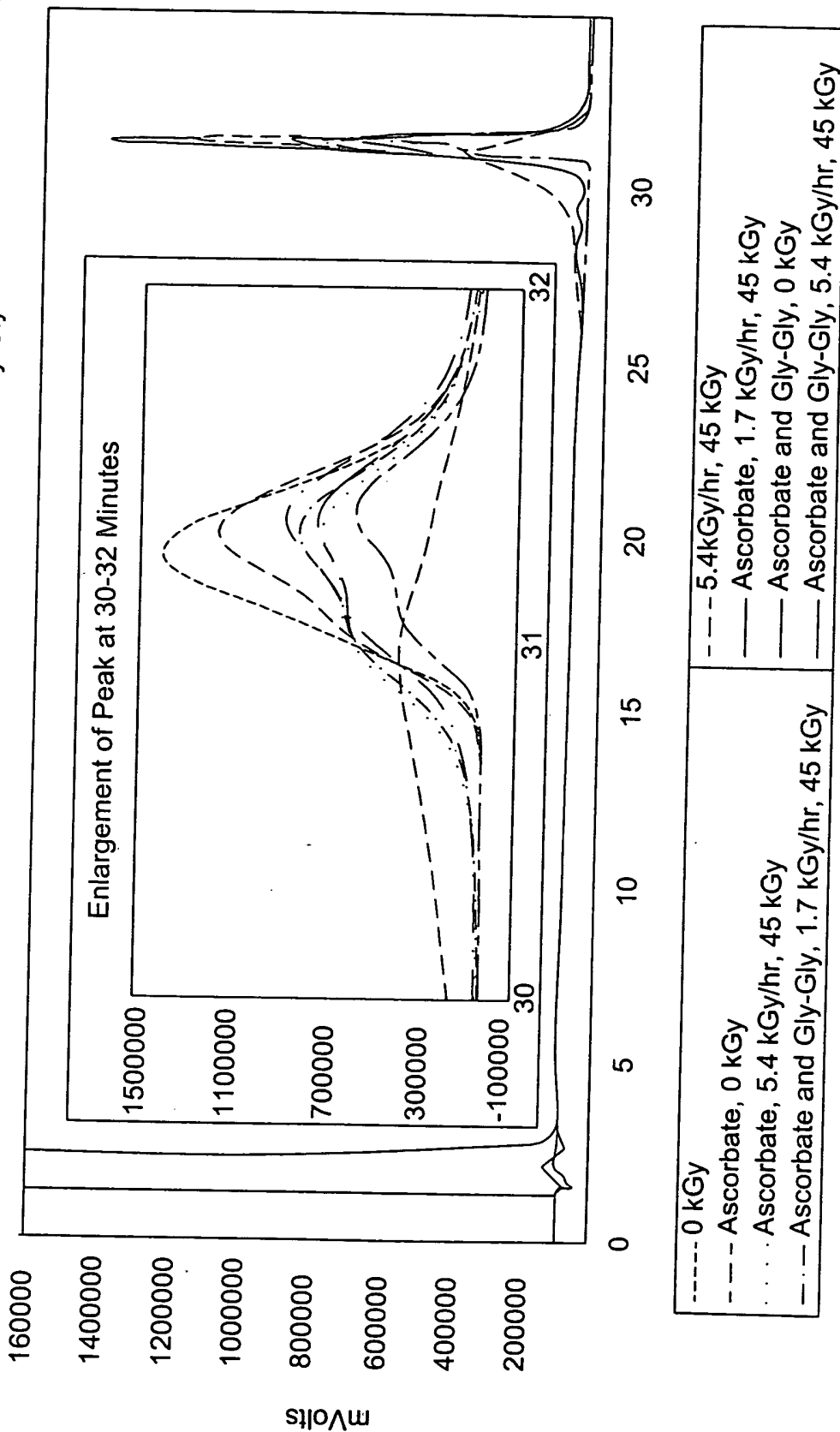


FIG. 47



110/113

Gamma Irradiation of a Lyophilized Glycosidase  
and Sulfatase In the Absence and Presence of  
100mM Ascorbate

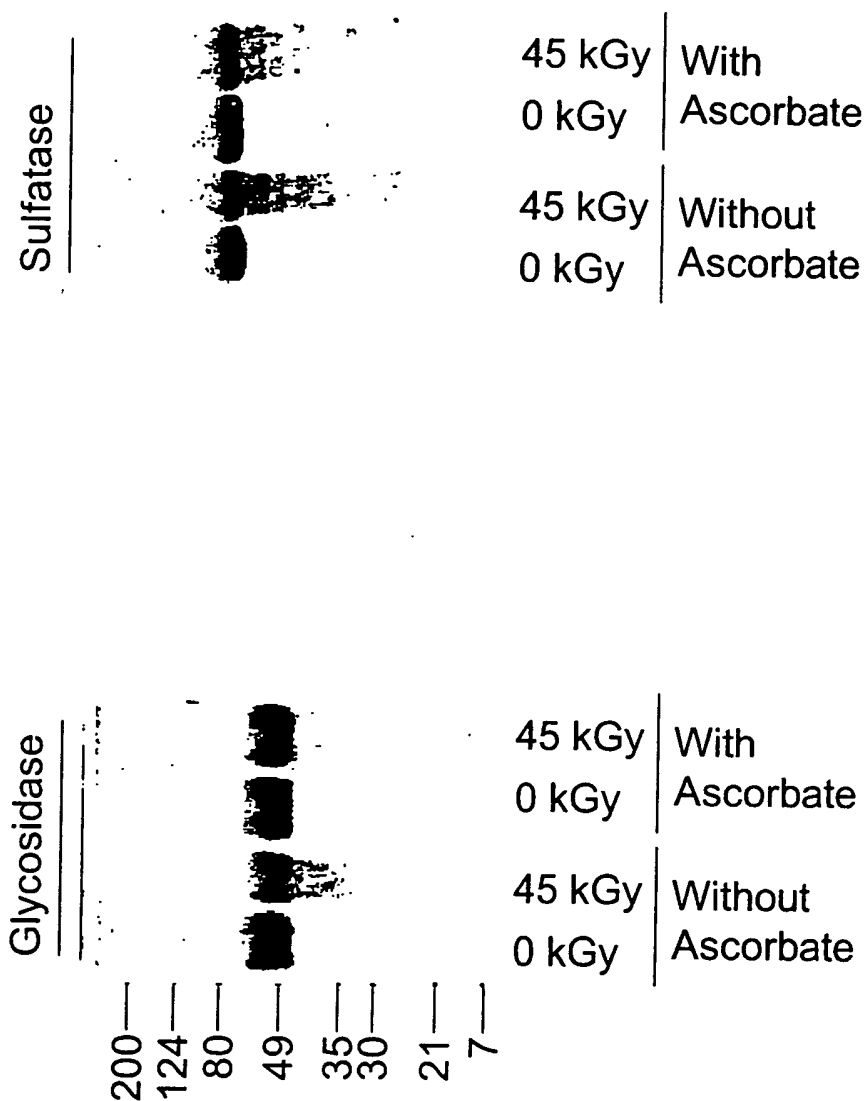


FIG. 48



111/113

# Gamma Irradiation of a Lyophilized Glycosidase In the Absence of Stabilizers

Reduced & Non-Reduced, 10%

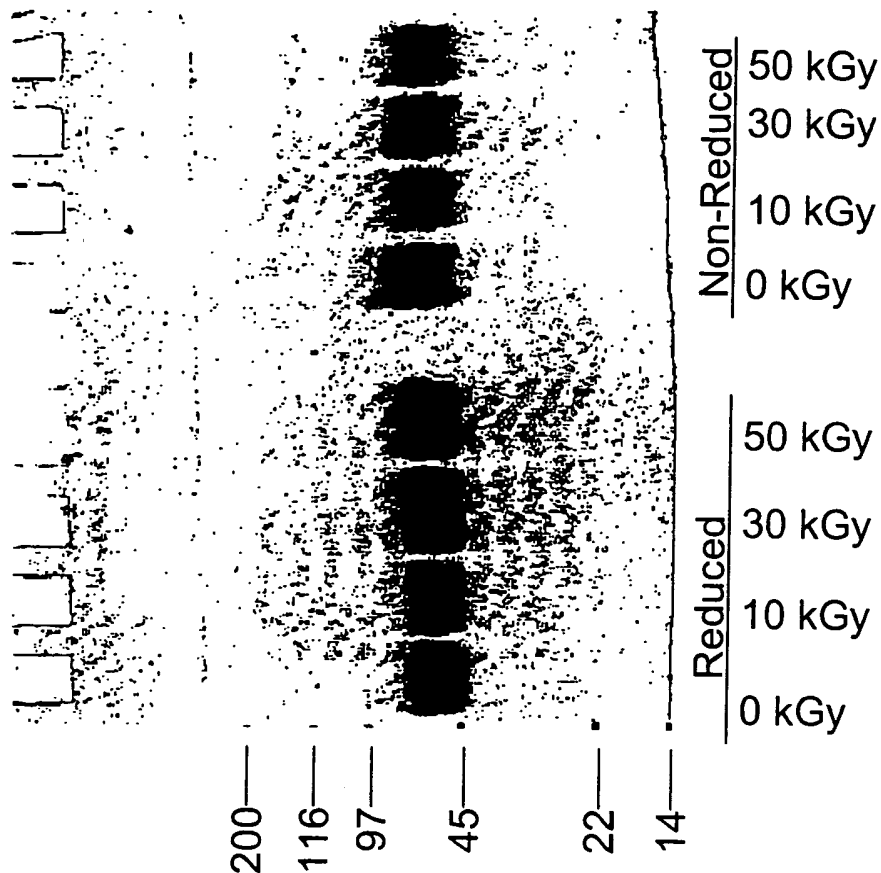


FIG. 49A

Gamma Irradiation of a Lyophilized Glycosidase  
 In the Presence of 200 mM Ascorbate

Reduced & Non-Reduced, 10%

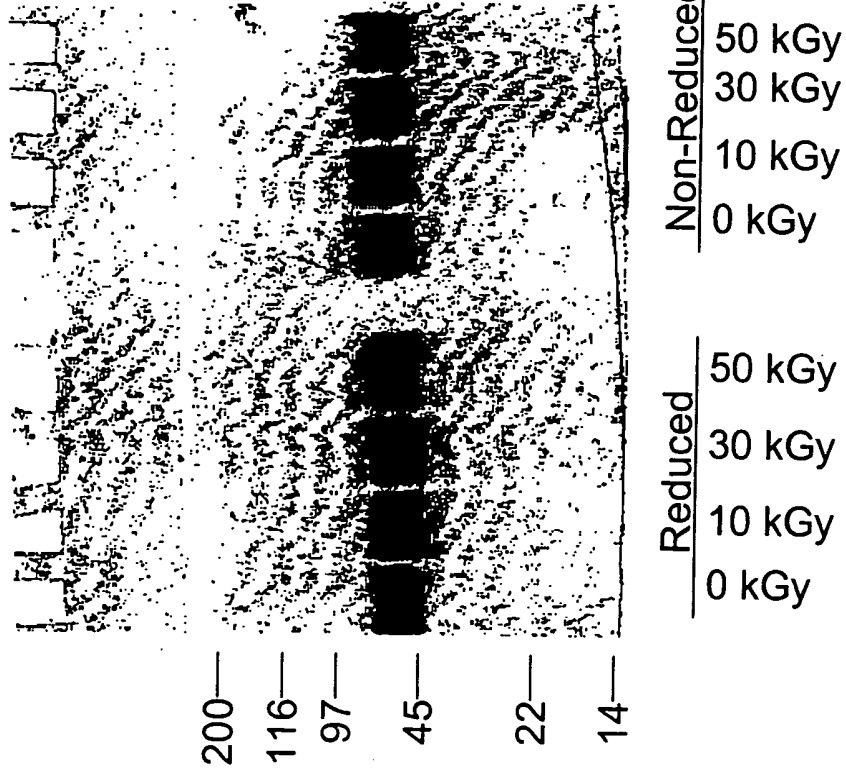


FIG. 49B



Gamma Irradiation of a Lyophilized Glycosidase  
 In the Presence of 200 mM Ascorbate and 200 mM Gly Gly

Reduced & Non-Reduced, 10%

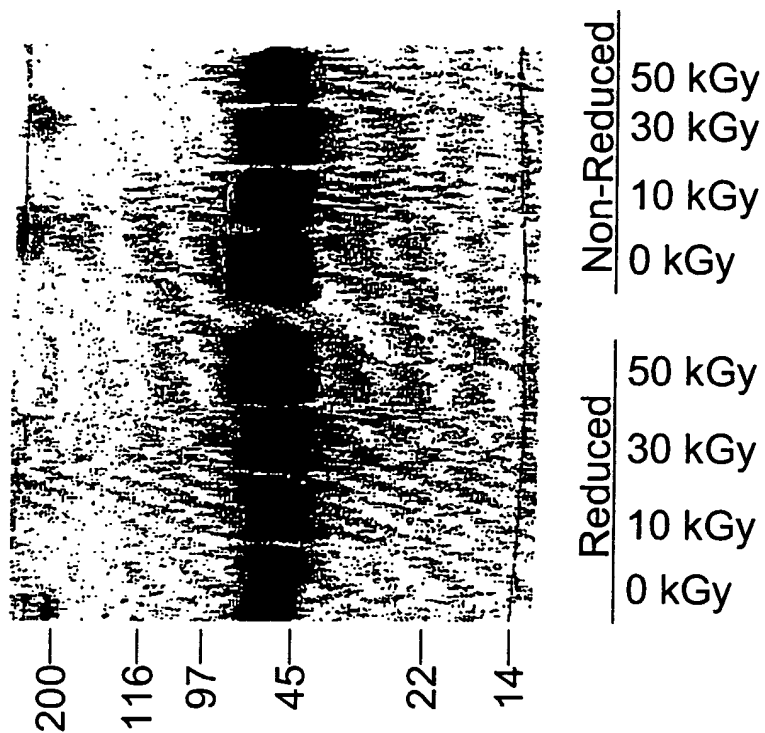


FIG. 49C